

117TH CONGRESS
2D SESSION

H. R. 7497

To provide for lower prices for drugs through drug price negotiation, and
for other purposes.

IN THE HOUSE OF REPRESENTATIVES

APRIL 11, 2022

Ms. SLOTKIN introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Education and Labor, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To provide for lower prices for drugs through drug price
negotiation, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Make Medicine Affordable Act”.

6 (b) TABLE OF CONTENTS.—The table of contents for
7 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—LOWERING PRICES THROUGH DRUG PRICE
NEGOTIATION

- Sec. 101. Providing for lower prices for certain high-priced single source drugs.
- Sec. 102. Selected drug manufacturer excise tax imposed during noncompliance periods.
- Sec. 103. Funding.

TITLE II—PRESCRIPTION DRUG INFLATION REBATES

- Sec. 201. Medicare part B rebate by manufacturers.
- Sec. 202. Medicare part D rebate by manufacturers.

TITLE III—PART D IMPROVEMENTS AND MAXIMUM OUT-OF-POCKET CAP FOR MEDICARE BENEFICIARIES

- Sec. 301. Medicare part D benefit redesign.
- Sec. 302. Maximum monthly cap on cost-sharing payments under prescription drug plans and MA–PD plans.

TITLE IV—REPEAL OF CERTAIN PRESCRIPTION DRUG REBATE RULE

- Sec. 401. Prohibiting implementation of rule relating to eliminating the anti-kickback statute safe harbor protection for prescription drug rebates.

TITLE V—MISCELLANEOUS

- Sec. 501. Appropriate cost-sharing for certain insulin products under Medicare part D.
- Sec. 502. Coverage of adult vaccines recommended by the Advisory Committee on Immunization Practices under Medicare part D.
- Sec. 503. Payment for biosimilar biological products during initial period.
- Sec. 504. Temporary increase in Medicare part B payment for certain biosimilar biological products.
- Sec. 505. Improving access to adult vaccines under Medicaid and CHIP.

TITLE VI—ADDITIONAL INSULIN POLICIES

- Sec. 601. ERISA requirements with respect to cost-sharing for certain insulin products.
- Sec. 602. Public Health Service Act requirements with respect to cost-sharing for insulin products.
- Sec. 603. IRC requirements with respect to cost-sharing for certain insulin products.

1 **TITLE I—LOWERING PRICES**
2 **THROUGH DRUG PRICE NE-**
3 **GOTIATION**

4 **SEC. 101. PROVIDING FOR LOWER PRICES FOR CERTAIN**
5 **HIGH-PRICED SINGLE SOURCE DRUGS.**

6 (a) PROGRAM TO LOWER PRICES FOR CERTAIN
7 HIGH-PRICED SINGLE SOURCE DRUGS.—Title XI of the
8 Social Security Act is amended by adding after section
9 1184 (42 U.S.C. 1320e–3) the following new part:

10 **“PART E—PRICE NEGOTIATION PROGRAM TO**
11 **LOWER PRICES FOR CERTAIN HIGH-PRICED**
12 **SINGLE SOURCE DRUGS**

13 **“SEC. 1191. ESTABLISHMENT OF PROGRAM.**

14 “(a) IN GENERAL.—The Secretary shall establish a
15 Drug Price Negotiation Program (in this part referred to
16 as the ‘program’). Under the program, with respect to
17 each price applicability period, the Secretary shall—

18 “(1) publish a list of negotiation-eligible drugs
19 and selected drugs in accordance with section 1192;

20 “(2) enter into agreements with manufacturers
21 of selected drugs with respect to such period, in ac-
22 cordance with section 1193;

23 “(3) negotiate and, if applicable, renegotiate
24 maximum fair prices for such selected drugs, in ac-
25 cordance with section 1194; and

1 “(4) carry out the administrative duties de-
2 scribed in section 1196.

3 “(b) DEFINITIONS RELATING TO TIMING.—For pur-
4 poses of this part:

5 “(1) INITIAL PRICE APPLICABILITY YEAR.—The
6 term ‘initial price applicability year’ means a year
7 (beginning with 2025).

8 “(2) PRICE APPLICABILITY PERIOD.—The term
9 ‘price applicability period’ means, with respect to a
10 qualifying single source drug, the period beginning
11 with the first initial price applicability year with re-
12 spect to which such drug is a selected drug and end-
13 ing with the last year during which the drug is a se-
14 lected drug.

15 “(3) SELECTED DRUG PUBLICATION DATE.—
16 The term ‘selected drug publication date’ means,
17 with respect to each initial price applicability year,
18 February 1 of the year that begins 2 years prior to
19 such year.

20 “(4) NEGOTIATION PERIOD.—The term ‘nego-
21 tiation period’ means, with respect to an initial price
22 applicability year with respect to a selected drug, the
23 period—

24 “(A) beginning on the sooner of—

1 “(i) the date on which the manufac-
2 turer of the drug and the Secretary enter
3 into an agreement under section 1193 with
4 respect to such drug; or

5 “(ii) February 28 following the se-
6 lected drug publication date with respect to
7 such selected drug; and

8 “(B) ending on November 1 of the year
9 that begins 2 years prior to the initial price ap-
10 plicability year.

11 “(c) OTHER DEFINITIONS.—For purposes of this
12 part:

13 “(1) MAXIMUM FAIR PRICE ELIGIBLE INDIVIDUAL.—The term ‘maximum fair price eligible in-
14 dividual’ means, with respect to a selected drug—

16 “(A) in the case such drug is dispensed to
17 the individual at a pharmacy, by a mail order
18 service, or by another dispenser, an individual
19 who is enrolled under a prescription drug plan
20 under part D of title XVIII or an MA–PD plan
21 under part C of such title if coverage is pro-
22 vided under such plan for such selected drug;
23 and

24 “(B) in the case such drug is furnished or
25 administered to the individual by a hospital,

1 physician, or other provider of services or sup-
2 plier, an individual who is enrolled under part
3 B of title XVIII, including an individual who is
4 enrolled under an MA plan under part C of
5 such title, if such selected drug is covered under
6 such part.

7 “(2) MAXIMUM FAIR PRICE.—The term ‘max-
8 imum fair price’ means, with respect to a year dur-
9 ing a price applicability period and with respect to
10 a selected drug (as defined in section 1192(c)) with
11 respect to such period, the price published pursuant
12 to section 1195 in the Federal Register for such
13 drug and year.

14 “(3) UNIT.—The term ‘unit’ means, with re-
15 spect to a drug or biological, the lowest identifiable
16 amount (such as a capsule or tablet, milligram of
17 molecules, or grams) of the drug or biological that
18 is dispensed or furnished. The determination of a
19 unit, with respect to a drug or biological, pursuant
20 to this paragraph shall not be subject to administra-
21 tive or judicial review.

22 “(4) TOTAL EXPENDITURES.—The term ‘total
23 expenditures’ includes, in the case of expenditures
24 with respect to part D of title XVIII, ingredient
25 costs, dispensing fees, sales tax, and if applicable,

1 vaccine administration fees. The term ‘total expendi-
 2 tures’ excludes, in the case of expenditures with re-
 3 spect to part B of such title, expenditures for a drug
 4 or biological that are bundled or packaged into the
 5 payment for another service.

6 **“SEC. 1192. SELECTION OF NEGOTIATION-ELIGIBLE DRUGS**
 7 **AS SELECTED DRUGS.**

8 “(a) IN GENERAL.—Not later than the selected drug
 9 publication date with respect to an initial price applica-
 10 bility year, in accordance with subsection (b), the Sec-
 11 retary shall select and publish in the Federal Register a
 12 list of—

13 “(1)(A) with respect to the initial price applica-
 14 bility year 2025, not more than 10 negotiation-eligi-
 15 ble drugs described in subparagraph (A)(i) of sub-
 16 section (d)(1), but not subparagraph (B) of such
 17 subsection, with respect to such year;

18 “(B) with respect to the initial price applica-
 19 bility year 2026, not more than 15 negotiation-eligi-
 20 ble drugs described in subparagraph (A)(i) of sub-
 21 section (d)(1), but not subparagraph (B) of such
 22 subsection, with respect to such year;

23 “(C) with respect to the initial price applica-
 24 bility year 2027, not more than 15 negotiation-eligi-
 25 ble drugs described in subparagraph (A) of sub-

1 section (d)(1), but not subparagraph (B) of such
2 subsection, with respect to such year; and

3 “(D) with respect to the initial price applica-
4 bility year 2028 or a subsequent year, not more than
5 20 negotiation-eligible drugs described in subpara-
6 graph (A) of subsection (d)(1), but not subpara-
7 graph (B) of such subsection, with respect to such
8 year; and

9 “(2) all negotiation-eligible drugs described in
10 subparagraph (B) of such subsection with respect to
11 such year.

12 Subject to subsection (c)(2) and section 1194(f)(5), each
13 drug published on the list pursuant to the previous sen-
14 tence shall be subject to the negotiation process under sec-
15 tion 1194 for the negotiation period with respect to such
16 initial price applicability year (and the renegotiation proc-
17 ess under such section as applicable for any subsequent
18 year during the applicable price applicability period).

19 “(b) SELECTION OF DRUGS.—

20 “(1) IN GENERAL.—In carrying out subsection
21 (a)(1), subject to paragraph (2), the Secretary shall,
22 with respect to an initial price applicability year—

23 “(A) rank a combined list of negotiation-el-
24 igible drugs described in subsection (d)(1)(A)
25 according to the total expenditures for such

1 drugs under parts B and D of title XVIII, as
2 determined by the Secretary, during the most
3 recent period of 12 months prior to the selected
4 drug publication date (but ending not later
5 than October 31 of the year prior to the year
6 of such drug publication date), with respect to
7 such year, for which data are available, with the
8 negotiation-eligible drugs with the highest total
9 expenditures being ranked the highest; and

10 “(B) select from such ranked combined list
11 for inclusion on the published list described in
12 subsection (a) with respect to such year the ne-
13 gotiation-eligible drugs with the highest such
14 rankings.

15 “(2) HIGH SPEND PART D DRUGS FOR 2025 AND
16 2026.—With respect to the initial price applicability
17 year 2025 and with respect to the initial price appli-
18 cability year 2026, the Secretary shall apply para-
19 graph (1) as if the reference to ‘negotiation-eligible
20 drugs described in subsection (d)(1)(A)’ were a ref-
21 erence to ‘negotiation-eligible drugs described in sub-
22 section (d)(1)(A)(i)’ and as if the reference to ‘total
23 expenditures for such drugs under parts B and D of
24 title XVIII’ were a reference to ‘total expenditures
25 for such drugs under part D of title XVIII’.

1 “(c) SELECTED DRUG.—

2 “(1) IN GENERAL.—For purposes of this part,
3 consistent with subsection (e)(2) and subject to
4 paragraph (2), each negotiation-eligible drug in-
5 cluded on the list published under subsection (a)
6 with respect to an initial price applicability year
7 shall be referred to as a ‘selected drug’ with respect
8 to such year and each subsequent year beginning be-
9 fore the first year that begins after the date on
10 which the Secretary determines at least one drug or
11 biological product—

12 “(A) is approved or licensed (as applica-
13 ble)—

14 “(i) under section 505(j) of the Fed-
15 eral Food, Drug, and Cosmetic Act using
16 such drug as the listed drug; or

17 “(ii) under section 351(k) of the Pub-
18 lic Health Service Act using such drug as
19 the reference product; and

20 “(B) is marketed pursuant to such ap-
21 proval or licensure.

22 “(2) CLARIFICATION.—A negotiation-eligible
23 drug—

1 “(A) that is included on the list published
2 under subsection (a) with respect to an initial
3 price applicability year; and

4 “(B) for which the Secretary makes a de-
5 termination described in paragraph (1) before
6 or during the negotiation period with respect to
7 such initial price applicability year,

8 shall not be subject to the negotiation process under
9 section 1194 with respect to such negotiation period
10 and shall continue to be considered a selected drug
11 under this part with respect to the number of nego-
12 tiation-eligible drugs published on the list under sub-
13 section (a) with respect to such initial price applica-
14 bility year.

15 “(d) NEGOTIATION-ELIGIBLE DRUG.—

16 “(1) IN GENERAL.—For purposes of this part,
17 subject to paragraph (2), the term ‘negotiation-eli-
18 ble drug’ means, with respect to the selected drug
19 publication date with respect to an initial price ap-
20 plicability year, a qualifying single source drug, as
21 defined in subsection (e), that is described in either
22 of the following subparagraphs (or, with respect to
23 the initial price applicability year 2025 or 2026, that
24 is described in subparagraph (A)(i) or (B)):

1 “(A) HIGH SPEND DRUGS.—The qualifying
2 single source drug is, determined in accordance
3 with subsection (e)(2)—

4 “(i) among the 50 qualifying single
5 source drugs with the highest total expend-
6 itures under part D of title XVIII, as de-
7 termined by the Secretary in accordance
8 with paragraph (3), during the most recent
9 period for which data are available of at
10 least 12 months prior to the selected drug
11 publication date (but ending no later than
12 October 31 of the year prior to the year of
13 such drug publication date), with respect
14 to such year; or

15 “(ii) among the 50 qualifying single
16 source drugs with the highest total expend-
17 itures under part B of title XVIII, as de-
18 termined by the Secretary in accordance
19 with paragraph (3), during such most re-
20 cent period, as described in clause (i).

21 “(B) INSULIN.—The qualifying single
22 source drug is described in subsection (e)(1)(C).

23 “(2) EXCEPTION FOR SMALL BIOTECH
24 DRUGS.—

1 “(A) IN GENERAL.—Subject to subpara-
2 graph (C), the term ‘negotiation-eligible drug’
3 shall not include, with respect to the initial
4 price applicability years 2025, 2026, and 2027,
5 a qualifying single source drug that meets ei-
6 ther of the following:

7 “(i) PART D DRUGS.—The total ex-
8 penditures for the qualifying single source
9 drug under part D of title XVIII, as deter-
10 mined by the Secretary in accordance with
11 paragraph (3), during 2021—

12 “(I) are equal to or less than 1
13 percent of the total expenditures
14 under such part D, as so determined,
15 for all covered part D drugs during
16 such year; and

17 “(II) are equal to at least 80 per-
18 cent of the total expenditures under
19 such part D, as so determined, for all
20 covered part D drugs for which the
21 manufacturer of the drug has an
22 agreement in effect under section
23 1860D–14A during such year.

24 “(ii) PART B DRUGS.—The total ex-
25 penditures for the qualifying single source

1 drug under part B of title XVIII, as deter-
2 mined by the Secretary in accordance with
3 paragraph (3), during 2021—

4 “(I) are equal to or less than 1
5 percent of the total expenditures
6 under such part B, as so determined,
7 for all qualifying single source drugs
8 covered under such part B during
9 such year; and

10 “(II) are equal to at least 80 per-
11 cent of the total expenditures under
12 such part B, as so determined, for all
13 qualifying single source drugs of the
14 manufacturer that are covered under
15 such part B during such year.

16 “(B) CLARIFICATIONS RELATING TO MAN-
17 UFACTURERS.—

18 “(i) AGGREGATION RULE.—All per-
19 sons treated as a single employer under
20 subsection (a) or (b) of section 52 of the
21 Internal Revenue Code of 1986 shall be
22 treated as one manufacturer for purposes
23 of this paragraph.

24 “(ii) LIMITATION.—A qualifying sin-
25 gle source drug described in subparagraph

1 (A) shall not include a qualifying single
2 source drug of a manufacturer if such
3 manufacturer is acquired after 2021 by
4 another manufacturer that does not meet
5 the definition of a specified manufacturer
6 under section 1860D–14C(g)(4)(B)(ii), ef-
7 fective at the beginning of the plan year
8 immediately following such acquisition or,
9 in the case of an acquisition before 2024,
10 effective January 1, 2024.

11 “(C) DRUGS NOT INCLUDED AS SMALL
12 BIOTECH DRUGS.—The following shall not be
13 considered a qualifying single source drug de-
14 scribed in subparagraph (A):

15 “(i) A vaccine that is licensed under
16 section 351 of the Public Health Service
17 Act and is marketed pursuant to such sec-
18 tion.

19 “(ii) A new formulation, such as an
20 extended release formulation, of a quali-
21 fying single source drug.

22 “(iii) A qualifying single source drug
23 described in subsection (e)(1)(C).

24 “(3) CLARIFICATIONS AND DETERMINATIONS.—

1 “(A) PREVIOUSLY SELECTED DRUGS AND
2 SMALL BIOTECH DRUGS EXCLUDED.—In apply-
3 ing clauses (i) and (ii) of paragraph (1)(A), the
4 Secretary shall not consider or count—

5 “(i) drugs that are already selected
6 drugs; and

7 “(ii) for initial price applicability
8 years 2025, 2026, and 2027, qualifying
9 single source drugs described in paragraph
10 (2)(A).

11 “(B) USE OF DATA.—In determining
12 whether a qualifying single source drug satisfies
13 any of the criteria described in paragraph (1)
14 or (2), the Secretary shall use data that is ag-
15 gregated across dosage forms and strengths of
16 the drug, including new formulations of the
17 drug, such as an extended release formulation,
18 and not based on the specific formulation or
19 package size or package type of the drug.

20 “(4) PUBLICATION.—Not later than the se-
21 lected drug publication date with respect to an ini-
22 tial price applicability year, the Secretary shall pub-
23 lish in the Federal Register a list of negotiation-eli-
24 gible drugs with respect to such selected drug publi-
25 cation date.

1 “(e) QUALIFYING SINGLE SOURCE DRUG.—

2 “(1) IN GENERAL.—For purposes of this part,
3 the term ‘qualifying single source drug’ means, with
4 respect to an initial price applicability year, subject
5 to paragraphs (2) and (3), a covered part D drug
6 (as defined in section 1860D–2(e)) that is described
7 in any of the following or a drug or biological prod-
8 uct covered under part B of title XVIII that is de-
9 scribed in any of the following:

10 “(A) DRUG PRODUCTS.—A drug—

11 “(i) that is approved under section
12 505(c) of the Federal Food, Drug, and
13 Cosmetic Act and is marketed pursuant to
14 such approval;

15 “(ii) for which, as of the selected drug
16 publication date with respect to such initial
17 price applicability year, at least 7 years
18 will have elapsed since the date of such ap-
19 proval; and

20 “(iii) that is not the listed drug for
21 any drug that is approved and marketed
22 under section 505(j) of such Act.

23 “(B) BIOLOGICAL PRODUCTS.—A biologi-
24 cal product—

1 “(i) that is licensed under section
2 351(a) of the Public Health Service Act
3 and is marketed under section 351 of such
4 Act;

5 “(ii) for which, as of the selected drug
6 publication date with respect to such initial
7 price applicability year, at least 11 years
8 will have elapsed since the date of such li-
9 censure; and

10 “(iii) that is not the reference product
11 for any biological product that is licensed
12 and marketed under section 351(k) of such
13 Act.

14 “(C) INSULIN PRODUCT.—Any insulin
15 product that is approved under section 505 of
16 the Federal Food, Drug, and Cosmetic Act or
17 licensed under section 351 of the Public Health
18 Service Act and marketed pursuant to such ap-
19 proval or licensure, including any insulin prod-
20 uct that has been deemed to be licensed under
21 section 351 of the Public Health Service Act
22 pursuant to section 7002(e)(4) of the Biologics
23 Price Competition and Innovation Act of 2009
24 and is marketed pursuant to such section, re-

1 gardless of whether such insulin product would
2 be described in subparagraph (A) or (B).

3 “(2) TREATMENT OF AUTHORIZED GENERIC
4 DRUGS.—

5 “(A) IN GENERAL.—In the case of a quali-
6 fying single source drug described in subpara-
7 graph (A) or (B) of paragraph (1) that is the
8 listed drug (as such term is used in section
9 505(j) of the Federal Food, Drug, and Cos-
10 metic Act) or the reference product (as defined
11 in section 351(i) of the Public Health Service
12 Act), with respect to an authorized generic
13 drug, in applying the provisions of this part,
14 such authorized generic drug and such listed
15 drug or reference product shall be treated as
16 the same qualifying single source drug.

17 “(B) AUTHORIZED GENERIC DRUG DE-
18 FINED.—For purposes of this paragraph, the
19 term ‘authorized generic drug’ means—

20 “(i) in the case of a drug, an author-
21 ized generic drug (as such term is defined
22 in section 505(t)(3) of the Federal Food,
23 Drug, and Cosmetic Act); and

24 “(ii) in the case of a biological prod-
25 uct, a reference product (as such term is

1 defined in section 351(i) of the Public
2 Health Service Act) that—

3 “(I) has been licensed under sec-
4 tion 351(a) of such Act; and

5 “(II) is marketed, sold, or dis-
6 tributed directly or indirectly to retail
7 class of trade under a different label-
8 ing, packaging (other than repack-
9 aging as the reference product in blis-
10 ter packs, unit doses, or similar pack-
11 aging for use in institutions), product
12 code, labeler code, trade name, or
13 trade mark than the reference prod-
14 uct.

15 “(3) EXCLUSIONS.—In this part, the term
16 ‘qualifying single source drug’ does not include any
17 of the following:

18 “(A) CERTAIN ORPHAN DRUGS.—A drug
19 that is designated as a drug for only one rare
20 disease or condition under section 526 of the
21 Federal Food, Drug, and Cosmetic Act and for
22 which the only approved indication (or indica-
23 tions) is for such disease or condition.

24 “(B) LOW SPEND MEDICARE DRUGS.—A
25 drug or biological product (other than an insu-

lin product described in paragraph (1)(C)) with respect to which the total expenditures under parts B and D of title XVIII, as determined by the Secretary, during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year is less than—

“(i) with respect to 2021,
\$200,000,000; or

“(ii) with respect to a subsequent year, the dollar amount specified in this subparagraph for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of December of such previous year.

“(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW OF DETERMINATIONS AND SELECTIONS.—The determination of negotiation-eligible drugs under subsection (d) and the selection of drugs under this section are not subject to administrative or judicial review.

1 **“SEC. 1193. MANUFACTURER AGREEMENTS.**

2 “(a) IN GENERAL.—For purposes of section
3 1191(a)(2), the Secretary shall enter into agreements with
4 manufacturers of selected drugs with respect to a price
5 applicability period, by not later than February 28 fol-
6 lowing the selected drug publication date with respect to
7 such selected drug, under which—

8 “(1) during the negotiation period for the initial
9 price applicability year for the selected drug, the
10 Secretary and manufacturer, in accordance with sec-
11 tion 1194, negotiate to determine (and, by not later
12 than the last date of such period, agree to) a max-
13 imum fair price for such selected drug of the manu-
14 facturer in order for the manufacturer to provide ac-
15 cess to such price—

16 “(A) to maximum fair price eligible indi-
17 viduals who with respect to such drug are de-
18 scribed in subparagraph (A) of section
19 1191(c)(1) and are dispensed such drug (and to
20 pharmacies, mail order services, and other dis-
21 pensers, with respect to such maximum fair
22 price eligible individuals who are dispensed such
23 drugs) during, subject to subparagraph (2), the
24 price applicability period; and

25 “(B) to hospitals, physicians, and other
26 providers of services and suppliers with respect

1 to maximum fair price eligible individuals who
2 with respect to such drug are described in sub-
3 paragraph (B) of such section and are fur-
4 nished or administered such drug during, sub-
5 ject to subparagraph (2), the price applicability
6 period;

7 “(2) the Secretary and the manufacturer shall,
8 in accordance with section 1194, renegotiate (and,
9 by not later than the last date of such period, agree
10 to) the maximum fair price for such drug, in order
11 for the manufacturer to provide access to such max-
12 imum fair price (as so renegotiated)—

13 “(A) to maximum fair price eligible indi-
14 viduals who with respect to such drug are de-
15 scribed in subparagraph (A) of section
16 1191(c)(1) and are dispensed such drug (and to
17 pharmacies, mail order services, and other dis-
18 pensers, with respect to such maximum fair
19 price eligible individuals who are dispensed such
20 drugs) during any year during the price appli-
21 cability period (beginning after such renegoti-
22 ation) with respect to such selected drug; and

23 “(B) to hospitals, physicians, and other
24 providers of services and suppliers with respect
25 to maximum fair price eligible individuals who

1 with respect to such drug are described in sub-
2 paragraph (B) of such section and are fur-
3 nished or administered such drug during any
4 year described in subparagraph (A);

5 “(3) access to the maximum fair price (includ-
6 ing as renegotiated pursuant to paragraph (2)), with
7 respect to such a selected drug, shall be provided by
8 the manufacturer to—

9 “(A) maximum fair price eligible individ-
10 uals, who with respect to such drug are de-
11 scribed in subparagraph (A) of section
12 1191(c)(1), at the pharmacy, mail order service,
13 or other dispenser at the point-of-sale of such
14 drug (and shall be provided by the manufac-
15 turer to the pharmacy, mail order service, or
16 other dispenser, with respect to such maximum
17 fair price eligible individuals who are dispensed
18 such drugs), as described in paragraph (1)(A)
19 or (2)(A), as applicable; and

20 “(B) hospitals, physicians, and other pro-
21 viders of services and suppliers with respect to
22 maximum fair price eligible individuals who
23 with respect to such drug are described in sub-
24 paragraph (B) of such section and are fur-

1 nished or administered such drug, as described
2 in paragraph (1)(B) or (2)(B), as applicable;

3 “(4) the manufacturer, subject to subsection
4 (d), submits to the Secretary, through an online por-
5 tal established by the Secretary or other form and
6 manner specified by the Secretary, for the negotia-
7 tion period for the price applicability period (and, if
8 applicable, before any period of renegotiation pursu-
9 ant to section 1194(f)) with respect to such drug—

10 “(A) information on the non-Federal aver-
11 age manufacturer price for the drug for the ap-
12 plicable year or period; and

13 “(B) all other information that the Sec-
14 retary requires to carry out the negotiation (or
15 renegotiation process) under this part, including
16 information described in section 1194(e)(1);
17 and

18 “(5) the manufacturer complies with require-
19 ments imposed by the Secretary for purposes of ad-
20 ministering the program, including with respect to
21 the duties described in section 1196.

22 “(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO
23 LONGER A SELECTED DRUG.—An agreement entered into
24 under this section shall be effective, with respect to a se-

1 lected drug, until such drug is no longer considered a se-
 2 lected drug under section 1192(c).

3 “(c) CONFIDENTIALITY OF INFORMATION.—Informa-
 4 tion submitted to the Secretary under this part by a man-
 5 ufacturer of a selected drug that is proprietary informa-
 6 tion of such manufacturer (as determined by the Sec-
 7 retary) shall be used only by the Secretary or disclosed
 8 to and used by the Comptroller General of the United
 9 States or the Medicare Payment Advisory Commission for
 10 purposes of carrying out this part.

11 “(d) IMPLEMENTATION FOR 2025 AND 2026.—Not-
 12 withstanding any other provision of this part, the Sec-
 13 retary shall implement this section for 2025 and 2026 by
 14 program instruction or otherwise.

15 **“SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS.**

16 “(a) IN GENERAL.—For purposes of this part, under
 17 an agreement under section 1193 between the Secretary
 18 and a manufacturer of a selected drug, with respect to
 19 the period for which such agreement is in effect and in
 20 accordance with subsections (b), (c), and (d), the Sec-
 21 retary and the manufacturer—

22 “(1) shall during the negotiation period with re-
 23 spect to such drug, in accordance with this section,
 24 negotiate a maximum fair price for such drug for
 25 the purpose described in section 1193(a)(1); and

1 “(2) renegotiate, in accordance with the process
2 specified pursuant to subsection (f), such maximum
3 fair price for such drug if such drug is a renegoti-
4 ation-eligible drug under such subsection.

5 “(b) NEGOTIATION PROCESS REQUIREMENTS.—

6 “(1) METHODOLOGY AND PROCESS.—The Sec-
7 retary shall develop and use a consistent method-
8 ology and process, in accordance with paragraph (2),
9 for negotiations under subsection (a) that aims to
10 achieve the lowest maximum fair price for each se-
11 lected drug.

12 “(2) SPECIFIC ELEMENTS OF NEGOTIATION
13 PROCESS.—As part of the negotiation process under
14 this section, with respect to a selected drug and the
15 negotiation period with respect to the initial price
16 applicability year with respect to such drug, the fol-
17 lowing shall apply:

18 “(A) SUBMISSION OF INFORMATION.—Not
19 later than March 1 of the year of the selected
20 drug publication date, with respect to the se-
21 lected drug, the manufacturer of the drug shall
22 submit to the Secretary, in accordance with sec-
23 tion 1193(a)(4), the information described in
24 such section.

“(B) INITIAL OFFER BY SECRETARY.—Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of a selected drug with a written initial offer that contains the Secretary’s proposal for the maximum fair price of the drug and a list of the considerations described in section 1194(e) that were used in developing such offer.

“(C) RESPONSE TO INITIAL OFFER.—

“(i) IN GENERAL.—Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

“(ii) COUNTEROFFER REQUIREMENTS.—If a manufacturer proposes a counteroffer, such counteroffer—

“(I) shall be in writing; and

“(II) shall be justified based on the factors described in subsection (e).

“(D) RESPONSE TO COUNTEROFFER.—

After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

1 “(E) DEADLINE.—All negotiations shall
 2 end prior to the first day of November following
 3 the selected drug publication date, with respect
 4 to the initial price applicability year.

5 “(F) LIMITATIONS ON OFFER AMOUNT.—
 6 In negotiating the maximum fair price of a se-
 7 lected drug, with respect to an initial price ap-
 8 plicability year for the selected drug, and, as
 9 applicable, in renegotiating the maximum fair
 10 price for such drug, with respect to a subse-
 11 quent year during the price applicability period
 12 for such drug, the Secretary shall not offer (or
 13 agree to a counteroffer for) a maximum fair
 14 price for the selected drug that—

15 “(i) exceeds the ceiling determined
 16 under subsection (c) for the selected drug
 17 and year; or

18 “(ii) as applicable, is less than the
 19 floor determined under subsection (d) for
 20 the selected drug and year.

21 “(G) TREATMENT OF DETERMINATION.—
 22 The establishment of a maximum fair price
 23 under this section is not subject to administra-
 24 tive or judicial review.

25 “(c) CEILING FOR MAXIMUM FAIR PRICE.—

1 “(1) IN GENERAL.—The maximum fair price
2 negotiated under this section for a selected drug,
3 with respect to the first year of the price applica-
4 bility period with respect to such drug, shall not ex-
5 ceed the applicable percent described in paragraph
6 (2), with respect to such drug, of the following:

7 “(A) INITIAL PRICE APPLICABILITY YEAR
8 2025.—In the case of a selected drug with re-
9 spect to which such initial price applicability
10 year is 2025, the average of the non-Federal
11 average manufacturer price for such drug for
12 the first 3 calendar quarters of 2021 (or, in the
13 case that there is not a non-Federal average
14 manufacturer price available for such drug for
15 any of such first 3 calendar quarters of 2021,
16 for the first full year following the market entry
17 for such drug), increased by the percentage in-
18 crease in the consumer price index for all urban
19 consumers (all items; United States city aver-
20 age) from September 2021 (or such first full
21 year following the market entry), as applicable,
22 to the year prior to the selected drug publica-
23 tion date with respect to such initial price appli-
24 cability year.

1 “(B) INITIAL PRICE APPLICABILITY YEAR
2 2026 AND SUBSEQUENT YEARS.—In the case of
3 a selected drug with respect to which such ini-
4 tial price applicability year is 2026 or a subse-
5 quent year, the lower of—

6 “(i) the average of the non-Federal
7 average manufacturer price for such drug
8 for the first 3 calendar quarters of 2021
9 (or, in the case that there is not a non-
10 Federal average manufacturer price avail-
11 able for such drug for any of such first 3
12 calendar quarters of 2021, for the first full
13 year following the market entry for such
14 drug), increased by the percentage increase
15 in the consumer price index for all urban
16 consumers (all items; United States city
17 average) from September 2021 (or such
18 first full year following the market entry),
19 as applicable, to the year prior to the se-
20 lected drug publication date with respect to
21 such initial price applicability year; or

22 “(ii) the non-Federal average manu-
23 facturer price for such drug for the year
24 prior to the selected drug publication date

1 with respect to such initial price applica-
2 bility year.

3 “(2) APPLICABLE PERCENT DESCRIBED.—For
4 purposes of paragraph (1), the applicable percent
5 described in this paragraph is the following:

6 “(A) SHORT-MONOPOLY DRUGS.—With re-
7 spect to a selected drug (other than a post-ex-
8 clusivity drug and a long-monopoly drug), 75
9 percent.

10 “(B) POST-EXCLUSIVITY DRUGS.—With re-
11 spect to a post-exclusivity drug, 65 percent.

12 “(C) LONG-MONOPOLY DRUGS.—With re-
13 spect to a long-monopoly drug, 40 percent.

14 “(3) POST-EXCLUSIVITY DRUG DEFINED.—

15 “(A) IN GENERAL.—In this part, subject
16 to subparagraph (B), the term ‘post-exclusivity
17 drug’ means, with respect to an initial price ap-
18 plicability year, a selected drug for which at
19 least 12 years, but fewer than 16 years, have
20 elapsed since the date of approval of such drug
21 under section 505(c) of the Federal Food,
22 Drug, and Cosmetic Act or since the date of li-
23 censure of such drug under section 351(a) of
24 the Public Health Service Act, as applicable.

1 “(B) EXCLUSIONS.—The term ‘post-exclu-
2 sivity drug’ shall not include any of the fol-
3 lowing:

4 “(i) A vaccine that is licensed under
5 section 351 of the Public Health Service
6 Act and marketed pursuant to such sec-
7 tion.

8 “(ii) A selected drug that had an
9 agreement under this part with the Sec-
10 retary prior to the initial price applicability
11 year 2030.

12 “(C) CLARIFICATION.—Nothing in sub-
13 paragraph (B)(ii) shall limit the transition of a
14 selected drug described in paragraph (2)(A) to
15 a long-monopoly drug if the selected drug meets
16 the definition of a long-monopoly drug.

17 “(4) LONG-MONOPOLY DRUG DEFINED.—

18 “(A) IN GENERAL.—In this part, subject
19 to subparagraph (B), the term ‘long-monopoly
20 drug’ means, with respect to an initial price ap-
21 plicability year, a selected drug for which at
22 least 16 years have elapsed since the date of
23 approval of such drug under section 505(c) of
24 the Federal Food, Drug, and Cosmetic Act or
25 since the date of licensure of such drug under

1 section 351(a) of the Public Health Service Act,
2 as applicable.

3 “(B) EXCLUSION.—The term ‘long-monop-
4 oly drug’ shall not include a vaccine that is li-
5 censed under section 351 of the Public Health
6 Service Act and marketed pursuant to such sec-
7 tion.

8 “(5) NON-FEDERAL AVERAGE MANUFACTURER
9 PRICE.—In this part, the term ‘non-Federal average
10 manufacturer price’ has the meaning given such
11 term in section 8126(h)(5) of title 38, United States
12 Code.

13 “(d) TEMPORARY FLOOR FOR SMALL BIOTECH
14 DRUGS.—In the case of a selected drug that is a quali-
15 fying single source drug described in section 1192(d)(2)
16 and with respect to which the first initial price applica-
17 bility year of the price applicability period with respect to
18 such drug is 2028 or 2029, the maximum fair price nego-
19 tiated under this section for such drug for such initial
20 price applicability year may not be less than 66 percent
21 of the average of the non-Federal average manufacturer
22 price for such drug (as defined and applied in subsection
23 (c)(4)) for the first 3 calendar quarters of 2021 (or, in
24 the case that there is not a non-Federal average manufac-
25 turer price available for such drug for any of such first

1 3 calendar quarters of 2021, for the first full year fol-
2 lowing the market entry for such drug), increased by the
3 percentage increase in the consumer price index for all
4 urban consumers (all items; United States city average)
5 from September 2021 (or such first full year following the
6 market entry), as applicable, to the year prior to the se-
7 lected drug publication date with respect to the initial
8 price applicability year.

9 “(e) CONSIDERATIONS.—For purposes of negotiating
10 the maximum fair price of a selected drug under this part
11 with the manufacturer of the drug, the Secretary shall
12 consider the following factors (and, with respect to post-
13 exclusivity drugs and long-monopoly drugs, shall not con-
14 sider factors other than those described in subparagraphs
15 (B) and (C) of paragraph (1)):

16 “(1) MANUFACTURER-SPECIFIC INFORMA-
17 TION.—The following information, with respect to
18 such selected drug, including as submitted by the
19 manufacturer:

20 “(A) Research and development costs of
21 the manufacturer for the drug and the extent to
22 which the manufacturer has recouped research
23 and development costs.

24 “(B) Market data for the drug, including
25 the distribution of sales across different pro-

1 grams and purchasers and projected future rev-
2 enues for the drug.

3 “(C) Unit costs of production and distribu-
4 tion of the drug.

5 “(D) Prior Federal financial support for
6 novel therapeutic discovery and development
7 with respect to the drug.

8 “(E) Data on patents and on existing and
9 pending exclusivity for the drug.

10 “(F) National sales data for the drug.

11 “(G) Information on clinical trials for the
12 drug.

13 “(2) INFORMATION ON UNMET MEDICAL NEEDS
14 AND ALTERNATIVE TREATMENTS.—The following in-
15 formation, with respect to such selected drug:

16 “(A) The extent to which the drug rep-
17 resents a therapeutic advance as compared to
18 existing therapeutic alternatives and, to the ex-
19 tent such information is available, the costs of
20 such existing therapeutic alternatives.

21 “(B) Information on approval by the Food
22 and Drug Administration of alternative drug
23 products or biological products.

24 “(C) Information on comparative effective-
25 ness analysis for such products, taking into

1 consideration the effects of such products on
2 specific populations, such as individuals with
3 disabilities, the elderly, the terminally ill, chil-
4 dren, and other patient populations.

5 “(D) The extent to which the drug ad-
6 dresses unmet medical needs for a condition for
7 which treatment or diagnosis is not addressed
8 adequately by available therapy.

9 In considering information described in subpara-
10 graph (C), the Secretary shall not use evidence or
11 findings from comparative clinical effectiveness re-
12 search in a manner that treats extending the life of
13 an elderly, disabled, or terminally ill individual as of
14 lower value than extending the life of an individual
15 who is younger, nondisabled, or not terminally ill.

16 “(3) ADDITIONAL INFORMATION.—Information
17 submitted to the Secretary, in accordance with a
18 process specified by the Secretary, by other parties
19 that are affected by the establishment of a maximum
20 fair price for the selected drug.

21 “(f) RENEGOTIATION PROCESS.—

22 “(1) IN GENERAL.—In the case of a renegoti-
23 ation-eligible drug (as defined in paragraph (2)) that
24 is selected under paragraph (3), the Secretary shall
25 provide for a process of renegotiation (for years (be-

ginning with 2027) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

“(2) RENEGOTIATION-ELIGIBLE DRUG DEFINED.—In this section, the term ‘renegotiation-eligible drug’ means a selected drug that is any of the following:

“(A) ADDITION OF NEW INDICATION.—A selected drug for which a new indication is added to the drug.

“(B) CHANGE OF STATUS TO A POST-EXCLUSIVITY DRUG.—A selected drug that is described in section 1192(d)(1)(A) that—

“(i) is not a post-exclusivity drug or a long-monopoly drug; and

“(ii) for which there is a change in status to that of a post-exclusivity drug.

“(C) CHANGE OF STATUS TO A LONG-MONOPOLY DRUG.—A selected drug that is described in section 1192(d)(1)(A) that—

“(i) is not a long-monopoly drug; and

“(ii) for which there is a change in status to that of a long-monopoly drug.

“(D) MATERIAL CHANGES.—A selected drug for which the Secretary determines there

1 has been a material change of factors described
2 in paragraph (1) or (2) of subsection (e).

3 “(3) SELECTION OF DRUGS FOR RENEGOTI-
4 ATION.—Each year the Secretary shall select among
5 renegotiation-eligible drugs for renegotiation as fol-
6 lows:

7 “(A) ALL POST-EXCLUSIVITY NEGOTIA-
8 TION-ELIGIBLE DRUGS.—The Secretary shall
9 select all renegotiation-eligible drugs described
10 in paragraph (2)(B).

11 “(B) ALL LONG-MONOPOLY NEGOTIATION-
12 ELIGIBLE DRUGS.—The Secretary shall select
13 all renegotiation-eligible drugs described in
14 paragraph (2)(C).

15 “(C) REMAINING DRUGS.—Among the re-
16 maining renegotiation-eligible drugs described
17 in subparagraphs (A) and (D) of paragraph (2),
18 the Secretary shall select renegotiation-eligible
19 drugs for which the Secretary expects renegoti-
20 ation is likely to result in a significant change
21 in the maximum fair price otherwise negotiated.

22 “(4) RENEGOTIATION PROCESS.—The Secretary
23 shall specify the process for renegotiation of max-
24 imum fair prices with the manufacturer of a renego-
25 tiation-eligible drug selected for renegotiation under

1 this subsection. Such process shall, to the extent
2 practicable, be consistent with the methodology and
3 process established under subsection (b) and in ac-
4 cordance with subsections (c) and (d), and for pur-
5 poses of applying subsections (c) and (d), the ref-
6 erence to the first initial price applicability year of
7 the price applicability period with respect to such
8 drug shall be treated as the first initial price appli-
9 cability year of such period for which the maximum
10 fair price established pursuant to such renegotiation
11 applies, including for applying subsection (c)(2)(B)
12 in the case of renegotiation-eligible drugs described
13 in paragraph (3)(A) of this subsection and sub-
14 section (c)(2)(C) in the case of renegotiation-eligible
15 drugs described in paragraph (3)(B) of this sub-
16 section.

17 “(5) CLARIFICATION.—A renegotiation-eligible
18 drug for which the Secretary makes a determination
19 described in section 1192(c)(1) before or during the
20 period of renegotiation shall not be subject to the re-
21 negotiation process under this section.

22 “(6) NO ADMINISTRATIVE OR JUDICIAL RE-
23 VIEW.—The determination of renegotiation-eligible
24 drugs under paragraph (2) and the selection of re-

1 negotiation-eligible drugs under paragraph (3) are
2 not subject to administrative or judicial review.

3 “(g) REQUEST FOR INFORMATION.—For purposes of
4 negotiating and, as applicable, renegotiating (including for
5 purposes of determining whether to renegotiate) the max-
6 imum fair price of a selected drug under this part with
7 the manufacturer of the drug, with respect to a price ap-
8 plicability period, and other relevant data for purposes of
9 this section—

10 “(1) the Secretary shall, not later than the se-
11 lected drug publication date with respect to the ini-
12 tial price applicability year of such period, request
13 drug pricing information from the manufacturer of
14 such selected drug, including information described
15 in subsection (e)(1); and

16 “(2) by not later than March 1 following the se-
17 lected drug publication date, the manufacturer of
18 such selected drug shall submit to the Secretary
19 such requested information in such form and man-
20 ner as the Secretary requires.

21 The Secretary shall request, from the manufacturer or
22 others, all additional information needed to carry out the
23 negotiation and renegotiation process under this section.

24 “(h) CLARIFICATION.—In no case shall the maximum
25 fair price negotiated under this section for a selected drug

1 that is a qualifying single source drug described in sub-
 2 paragraph (A) or (B) of section 1192(e)(1) apply before—

3 “(1) in the case the selected drug is a quali-
 4 fying single source drug described in such subpara-
 5 graph (A), the date that is 9 years after the date on
 6 which the drug was approved under section 505(c)
 7 of the Federal Food, Drug, and Cosmetic Act; and

8 “(2) in the case the selected drug is a quali-
 9 fying single source drug described in such subpara-
 10 graph (B), the date that is 13 years after the date
 11 on which the drug was licensed under section 351(a)
 12 of the Public Health Service Act.

13 “(i) IMPLEMENTATION FOR 2025 AND 2026.—Not-
 14 withstanding any other provision of this part, the Sec-
 15 retary shall implement this section for 2025 and 2026 by
 16 program instruction or otherwise.

17 **“SEC. 1195. PUBLICATION OF MAXIMUM FAIR PRICES.**

18 “(a) IN GENERAL.—With respect to an initial price
 19 applicability year and a selected drug with respect to such
 20 year—

21 “(1) not later than November 15 of the year
 22 that is 2 years prior to such initial price applicability
 23 year, the Secretary shall publish on CMS.gov the
 24 maximum fair price for such drug negotiated under
 25 this part with the manufacturer of such drug;

1 “(2) not later than November 30 of the year
 2 that is 2 years prior to such initial price applicability
 3 year, the Secretary shall publish in the Federal Reg-
 4 ister the maximum fair price for such drug described
 5 in paragraph (1); and

6 “(3) not later than March 1 of the year prior
 7 to such initial price applicability year, the Secretary
 8 shall publish in the Federal Register, subject to sec-
 9 tion 1193(c) and based on the considerations as de-
 10 scribed in section 1194(e), the explanation for the
 11 maximum fair price for such drug described in para-
 12 graphs (1) and (2).

13 “(b) UPDATES.—

14 “(1) SUBSEQUENT YEAR MAXIMUM FAIR
 15 PRICES.—For a selected drug, for each year subse-
 16 quent to first initial price applicability year of the
 17 price applicability period with respect to such drug,
 18 with respect to which an agreement for such drug is
 19 in effect under section 1193, not later than Novem-
 20 ber 30 of the year that is 2 years prior to such sub-
 21 sequent year, the Secretary shall publish in the Fed-
 22 eral Register the maximum fair price applicable to
 23 such drug and year, which shall be—

24 “(A) subject to subparagraph (B), the
 25 amount equal to the maximum fair price pub-

1 lished for such drug for the previous year, in-
 2 creased by the annual percentage increase in
 3 the consumer price index for all urban con-
 4 sumers (all items; U.S. city average) as of Sep-
 5 tember of such previous year; or

6 “(B) in the case the maximum fair price
 7 for such drug was renegotiated, for the first
 8 year for which such price as so renegotiated ap-
 9 plies, such renegotiated maximum fair price.

10 “(2) PRICES NEGOTIATED AFTER DEADLINE.—
 11 In the case of a selected drug with respect to an ini-
 12 tial price applicability year for which the maximum
 13 fair price is determined under this part after the
 14 date of publication under this section, the Secretary
 15 shall publish such maximum fair price in the Fed-
 16 eral Register by not later than 30 days after the
 17 date such maximum price is so determined.

18 **“SEC. 1196. ADMINISTRATIVE DUTIES; COORDINATION PRO-**
 19 **VISIONS.**

20 “(a) ADMINISTRATIVE DUTIES.—

21 “(1) IN GENERAL.—For purposes of section
 22 1191, the administrative duties described in this sec-
 23 tion are the following:

1 “(A) The establishment of procedures to
2 ensure that the maximum fair price for a se-
3 lected drug is applied before—

4 “(i) any coverage or financial assist-
5 ance under other health benefit plans or
6 programs that provide coverage or finan-
7 cial assistance for the purchase or provi-
8 sion of prescription drug coverage on be-
9 half of maximum fair price eligible individ-
10 uals; and

11 “(ii) any other discounts.

12 “(B) The establishment of procedures to
13 compute and apply the maximum fair price
14 across different strengths and dosage forms of
15 a selected drug and not based on the specific
16 formulation or package size or package type of
17 the drug.

18 “(C) The establishment of procedures to
19 carry out the provisions of this part, as applica-
20 ble, with respect to—

21 “(i) maximum fair price eligible indi-
22 viduals who are enrolled under a prescrip-
23 tion drug plan under part D of title XVIII
24 or an MA–PD plan under part C of such
25 title; and

1 “(ii) maximum fair price eligible indi-
2 viduals who are enrolled under part B of
3 such title, including who are enrolled under
4 an MA plan under part C of such title.

5 “(D) The establishment of a negotiation
6 process and renegotiation process in accordance
7 with section 1194, including a process for ac-
8 quiring information described in subsection (e)
9 of such section.

10 “(E) The establishment of an online portal
11 which manufacturers shall be required to use to
12 submit information described in section
13 1194(b)(2)(A).

14 “(F) The sharing with the Secretary of the
15 Treasury of such information as is necessary to
16 determine the tax imposed by section 4192 of
17 the Internal Revenue Code of 1986 (relating to
18 enforcement of this part).

19 “(G) The establishment of an attestation
20 and verification process for purposes of apply-
21 ing section 1192(d)(2)(B).

22 “(2) MONITORING COMPLIANCE.—The Sec-
23 retary shall monitor compliance by a manufacturer
24 with the terms of an agreement under section 1193,

1 including by establishing a mechanism through
2 which violations of such terms shall be reported.

3 “(b) IMPLEMENTATION FOR 2025 AND 2026.—Not-
4 withstanding any other provision of this part, the Sec-
5 retary shall implement this section for 2025 and 2026 by
6 program instruction or otherwise.

7 **“SEC. 1197. CIVIL MONETARY PENALTY.**

8 “(a) VIOLATIONS RELATING TO OFFERING OF MAX-
9 IMUM FAIR PRICE.—Any manufacturer of a selected drug
10 that has entered into an agreement under section 1193,
11 with respect to a year during the price applicability period
12 with respect to such drug, that does not provide access
13 to a price that is not more than the maximum fair price
14 (or a lesser price) for such drug for such year—

15 “(1) to a maximum fair price eligible individual
16 who with respect to such drug is described in sub-
17 paragraph (A) of section 1191(c)(1) and who is dis-
18 pensed such drug during such year (and to phar-
19 macies, mail order services, and other dispensers,
20 with respect to such maximum fair price eligible in-
21 dividuals who are dispensed such drugs); or

22 “(2) to a hospital, physician, or other provider
23 of services or supplier with respect to maximum fair
24 price eligible individuals who with respect to such
25 drug is described in subparagraph (B) of such sec-

1 tion and is furnished or administered such drug by
2 such hospital, physician, or provider or supplier dur-
3 ing such year,
4 shall be subject to a civil monetary penalty equal to ten
5 times the amount equal to the product of the number of
6 units of such drug so furnished, dispensed, or adminis-
7 tered during such year and the difference between the
8 price for such drug made available for such year by such
9 manufacturer with respect to such individual or hospital,
10 physician, provider of services, or supplier and the max-
11 imum fair price for such drug for such year.

12 “(b) VIOLATIONS OF CERTAIN TERMS OF AGREE-
13 MENT.—Any manufacturer of a selected drug that has en-
14 tered into an agreement under section 1193, with respect
15 to a year during the price applicability period with respect
16 to such drug, that is in violation of a requirement imposed
17 pursuant to section 1193(a)(5), including the requirement
18 to submit information pursuant to section 1193(a)(4),
19 shall be subject to a civil monetary penalty equal to
20 \$1,000,000 for each day of such violation.

21 “(c) FALSE INFORMATION.—Any manufacturer that
22 knowingly provides false information for the attestation
23 process or verification process established pursuant to sec-
24 tion 1196(a)(1)(H), shall be subject to a civil monetary

1 penalty equal to \$100,000,000 for each item of such false
2 information.

3 “(d) APPLICATION.—The provisions of section 1128A
4 (other than subsections (a) and (b)) shall apply to a civil
5 monetary penalty under this section in the same manner
6 as such provisions apply to a penalty or proceeding under
7 section 1128A(a).”.

8 (b) APPLICATION OF MAXIMUM FAIR PRICES AND
9 CONFORMING AMENDMENTS.—

10 (1) UNDER MEDICARE.—

11 (A) APPLICATION TO PAYMENTS UNDER
12 PART B.—Section 1847A(b)(1)(B) of the Social
13 Security Act (42 U.S.C. 1395w–3a(b)(1)(B)) is
14 amended by inserting “or in the case of such a
15 drug or biological that is a selected drug (as re-
16 ferred to in section 1192(c)), with respect to a
17 price applicability period (as defined in section
18 1191(b)(2)), 106 percent of the maximum fair
19 price (as defined in section 1191(c)(2)) applica-
20 ble for such drug and a year during such pe-
21 riod” after “paragraph (4)”.

22 (B) APPLICATION UNDER MA OF COST-
23 SHARING FOR PART B DRUGS BASED OFF OF
24 NEGOTIATED PRICE.—Section
25 1852(a)(1)(B)(iv) of the Social Security Act

1 (42 U.S.C. 1395w-22(a)(1)(B)(iv)) is amend-
2 ed—

3 (i) by redesignating subclause (VII) as
4 subclause (VIII); and

5 (ii) by inserting after subclause (VI)
6 the following subclause:

7 “(VII) A drug or biological that
8 is a selected drug (as referred to in
9 section 1192(c)).”.

10 (C) EXCEPTION TO PART D NON-INTER-
11 FERENCE.—Section 1860D-11(i) of the Social
12 Security Act (42 U.S.C. 1395w-111(i)) is
13 amended—

14 (i) in paragraph (1), by striking
15 “and” at the end;

16 (ii) in paragraph (2), by striking “or
17 institute a price structure for the reim-
18 bursement of covered part D drugs” and
19 inserting “for covered part D drugs; and”;
20 and

21 (iii) by adding at the end the fol-
22 lowing:

23 “(3) may not institute a price structure for the
24 reimbursement of covered part D drugs, except as
25 provided under part E of title XI.”.

1 (D) APPLICATION AS NEGOTIATED PRICE
2 UNDER PART D.—Section 1860D–2(d)(1) of the
3 Social Security Act (42 U.S.C. 1395w–
4 102(d)(1)) is amended—

5 (i) in subparagraph (B), by inserting
6 “, subject to subparagraph (D),” after
7 “negotiated prices”; and

8 (ii) by adding at the end the following
9 new subparagraph:

10 “(D) APPLICATION OF MAXIMUM FAIR
11 PRICE FOR SELECTED DRUGS.—In applying this
12 section, in the case of a covered part D drug
13 that is a selected drug (as referred to in section
14 1192(c)), with respect to a price applicability
15 period (as defined in section 1191(b)(2)), the
16 negotiated prices used for payment (as de-
17 scribed in this subsection) shall be no greater
18 than the maximum fair price (as defined in sec-
19 tion 1191(c)(2)) for such drug and for each
20 year during such period plus any dispensing
21 fees for such drug.”.

22 (E) COVERAGE OF SELECTED DRUGS.—
23 Section 1860D–4(b)(3) of the Social Security
24 Act (42 U.S.C. 1395w–104(b)(3)) is amended

1 by adding at the end the following new sub-
2 paragraph:

3 “(I) REQUIRED INCLUSION OF SELECTED
4 DRUGS.—For 2025 and each subsequent year,
5 the PDP sponsor offering a prescription drug
6 plan shall include each covered part D drug
7 that is a selected drug under section 1192 for
8 which an agreement for such drug is in effect
9 under section 1193 with respect to the year.”.

10 (F) INFORMATION FROM PRESCRIPTION
11 DRUG PLANS AND MA–PD PLANS REQUIRED.—

12 (i) PRESCRIPTION DRUG PLANS.—Sec-
13 tion 1860D–12(b) of the Social Security
14 Act (42 U.S.C. 1395w–112(b)) is amended
15 by adding at the end the following new
16 paragraph:

17 “(8) PROVISION OF INFORMATION RELATED TO
18 MAXIMUM FAIR PRICES.—Each contract entered into
19 with a PDP sponsor under this part with respect to
20 a prescription drug plan offered by such sponsor
21 shall require the sponsor to provide information to
22 the Secretary as requested by the Secretary in ac-
23 cordance with section 1194(g).”.

24 (ii) MA–PD PLANS.—Section
25 1857(f)(3) of the Social Security Act (42

1 U.S.C. 1395w-27(f)(3)) is amended by
 2 adding at the end the following new sub-
 3 paragraph:

4 “(E) PROVISION OF INFORMATION RE-
 5 LATED TO MAXIMUM FAIR PRICES.—Section
 6 1860D-12(b)(8).”.

7 (2) DRUG PRICE NEGOTIATION PROGRAM
 8 PRICES INCLUDED IN BEST PRICE.—Section
 9 1927(c)(1)(C) of the Social Security Act (42 U.S.C.
 10 1396r-8(c)(1)(C)) is amended—

11 (A) in clause (i)(VI), by striking “any
 12 prices charged” and inserting “subject to clause
 13 (ii)(V), any prices charged”; and

14 (B) in clause (ii)—

15 (i) in subclause (III), by striking at
 16 the end “; and”;

17 (ii) in subclause (IV), by striking at
 18 the end the period and inserting “; and”;
 19 and

20 (iii) by adding at the end the fol-
 21 lowing new subclause:

22 “(V) in the case of a rebate pe-
 23 riod and a covered outpatient drug
 24 that is a selected drug (as referred to
 25 in section 1192(c)) during such rebate

1 period, shall be inclusive of the max-
 2 imum fair price (as defined in section
 3 1191(c)(2)) for such drug with re-
 4 spect to such period.”.

5 **SEC. 102. SELECTED DRUG MANUFACTURER EXCISE TAX**
 6 **IMPOSED DURING NONCOMPLIANCE PERI-**
 7 **ODS.**

8 (a) IN GENERAL.—Chapter 32 of the Internal Rev-
 9 enue Code of 1986 is amended by adding at the end the
 10 following new subchapter:

11 **“Subchapter E—Other Items**

“Sec. 4192. Selected drugs during noncompliance periods.

12 **“SEC. 4192. SELECTED DRUGS DURING NONCOMPLIANCE**
 13 **PERIODS.**

14 “(a) IN GENERAL.—There is hereby imposed on the
 15 sale by the manufacturer, producer, or importer of any
 16 selected drug during a day described in subsection (b) a
 17 tax in an amount such that the applicable percentage is
 18 equal to the ratio of—

19 “(1) such tax, divided by

20 “(2) the sum of such tax and the price for
 21 which so sold.

22 “(b) NONCOMPLIANCE PERIODS.—A day is described
 23 in this subsection with respect to a selected drug if it is
 24 a day during one of the following periods:

1 “(1) The period beginning on the March 1st
2 immediately following the selected drug publication
3 date and ending on the first date during which the
4 manufacturer of the drug has in place an agreement
5 described in subsection (a) of section 1193 of the
6 Social Security Act with respect to such drug.

7 “(2) The period beginning on the November
8 2nd immediately following the March 1st described
9 in paragraph (1) and ending on the first date during
10 which the manufacturer of the drug and the Sec-
11 retary have agreed to a maximum fair price under
12 such agreement.

13 “(3) In the case of a selected drug with respect
14 to which the Secretary of Health and Human Serv-
15 ices has specified a renegotiation period under such
16 agreement, the period beginning on the first date
17 after the last date of such renegotiation period and
18 ending on the first date during which the manufac-
19 turer of the drug has agreed to a renegotiated max-
20 imum fair price under such agreement.

21 “(4) With respect to information that is re-
22 quired to be submitted to the Secretary of Health
23 and Human Services under such agreement, the pe-
24 riod beginning on the date on which such Secretary

1 certifies that such information is overdue and ending
2 on the date that such information is so submitted.

3 “(c) APPLICABLE PERCENTAGE.—For purposes of
4 this section, the term ‘applicable percentage’ means—

5 “(1) in the case of sales of a selected drug dur-
6 ing the first 90 days described in subsection (b) with
7 respect to such drug, 65 percent,

8 “(2) in the case of sales of such drug during
9 the 91st day through the 180th day described in
10 subsection (b) with respect to such drug, 75 percent,

11 “(3) in the case of sales of such drug during
12 the 181st day through the 270th day described in
13 subsection (b) with respect to such drug, 85 percent,
14 and

15 “(4) in the case of sales of such drug during
16 any subsequent day, 95 percent.

17 “(d) SELECTED DRUG.—For purposes of this sec-
18 tion—

19 “(1) IN GENERAL.—The term ‘selected drug’
20 means any selected drug (within the meaning of sec-
21 tion 1192 of the Social Security Act) which is manu-
22 factured or produced in the United States or entered
23 into the United States for consumption, use, or
24 warehousing.

1 “(2) UNITED STATES.—The term ‘United
2 States’ has the meaning given such term by section
3 4612(a)(4).

4 “(3) COORDINATION WITH RULES FOR POSSES-
5 SIONS OF THE UNITED STATES.—Rules similar to
6 the rules of paragraphs (2) and (4) of section
7 4132(c) shall apply for purposes of this section.

8 “(e) OTHER DEFINITIONS.—For purposes of this
9 section, the terms ‘selected drug publication date’ and
10 ‘maximum fair price’ have the meaning given such terms
11 in section 1191 of the Social Security Act.

12 “(f) ANTI-ABUSE RULE.—In the case of a sale which
13 was timed for the purpose of avoiding the tax imposed by
14 this section, the Secretary may treat such sale as occur-
15 ring during a day described in subsection (b).”.

16 (b) NO DEDUCTION FOR EXCISE TAX PAYMENTS.—
17 Section 275(a)(6) of the Internal Revenue Code of 1986
18 is amended by inserting “or by section 4192” before the
19 period at the end.

20 (c) CERTAIN EXEMPTIONS FROM TAX NOT APPLICA-
21 BLE.—

22 (1) Section 4221(a) of the Internal Revenue
23 Code of 1986 is amended by adding at the end the
24 following: “In the case of the tax imposed by section

1 4192, paragraphs (3), (4), (5), and (6) shall not
2 apply.”.

3 (2) Section 6416(b)(2) of such Code is amend-
4 ed by adding at the end the following: “In the case
5 of the tax imposed by section 4192, subparagraphs
6 (B), (C), (D), and (E) shall not apply.”.

7 (d) CLERICAL AMENDMENT.—The table of sub-
8 chapters for chapter 32 of such Code is amended by add-
9 ing at the end the following new item:

“SUBCHAPTER E. OTHER ITEMS”.

10 (e) EFFECTIVE DATE.—The amendments made by
11 this section shall apply to sales after the date of the enact-
12 ment of this Act.

13 **SEC. 103. FUNDING.**

14 In addition to amounts otherwise available, there is
15 appropriated for fiscal year 2022, out of any money in
16 the Treasury not otherwise appropriated, to remain avail-
17 able until expended—

18 (1) \$300,000,000 to carry out the provisions of,
19 including the amendments made by, this part in fis-
20 cal year 2022;

21 (2) \$300,000,000 to carry out the provisions of,
22 including the amendments made by, this part in fis-
23 cal year 2023;

1 (3) \$300,000,000 to carry out the provisions of,
2 including the amendments made by, this part in fis-
3 cal year 2024;

4 (4) \$300,000,000 to carry out the provisions of,
5 including the amendments made by, this part in fis-
6 cal year 2025;

7 (5) \$300,000,000 to carry out the provisions of,
8 including the amendments made by, this part in fis-
9 cal year 2026;

10 (6) \$300,000,000 to carry out the provisions of,
11 including the amendments made by, this part in fis-
12 cal year 2027;

13 (7) \$300,000,000 to carry out the provisions of,
14 including the amendments made by, this part in fis-
15 cal year 2028;

16 (8) \$300,000,000 to carry out the provisions of,
17 including the amendments made by, this part in fis-
18 cal year 2029;

19 (9) \$300,000,000 to carry out the provisions of,
20 including the amendments made by, this part in fis-
21 cal year 2030; and

22 (10) \$300,000,000 to carry out the provisions
23 of, including the amendments made by, this part in
24 fiscal year 2031.

1 **TITLE II—PRESCRIPTION DRUG**
2 **INFLATION REBATES**

3 **SEC. 201. MEDICARE PART B REBATE BY MANUFACTURERS.**

4 (a) IN GENERAL.—Section 1847A of the Social Secu-
5 rity Act (42 U.S.C. 1395w–3a) is amended—

6 (1) by redesignating subsection (h) as sub-
7 section (i) and by inserting after subsection (g) the
8 following subsection:

9 “(h) REBATE BY MANUFACTURERS FOR SINGLE
10 SOURCE DRUGS AND BIOLOGICALS WITH PRICES IN-
11 CREASING FASTER THAN INFLATION.—

12 “(1) REQUIREMENTS.—

13 “(A) SECRETARIAL PROVISION OF INFOR-
14 MATION.—Not later than 6 months after the
15 end of each calendar quarter beginning on or
16 after July 1, 2023, the Secretary shall, for each
17 part B rebatable drug, report to each manufac-
18 turer of such part B rebatable drug the fol-
19 lowing for such calendar quarter:

20 “(i) Information on the total number
21 of billing units of the billing and payment
22 code described in subparagraph (A)(i) of
23 paragraph (3) with respect to such drug
24 and calendar quarter.

1 “(ii) Information on the amount (if
2 any) of the excess average sales price in-
3 crease described in subparagraph (A)(ii) of
4 such paragraph for such drug and calendar
5 quarter.

6 “(iii) The rebate amount specified
7 under such paragraph for such part B
8 rebatable drug and calendar quarter.

9 “(B) MANUFACTURER REQUIREMENT.—
10 For each calendar quarter beginning on or after
11 July 1, 2023, the manufacturer of a part B
12 rebatable drug shall, for such drug, not later
13 than 30 days after the date of receipt from the
14 Secretary of the information described in sub-
15 paragraph (A) for such calendar quarter, pro-
16 vide to the Secretary a rebate that is equal to
17 the amount specified in paragraph (3) for such
18 drug for such calendar quarter.

19 “(2) PART B REBATABLE DRUG DEFINED.—

20 “(A) IN GENERAL.—In this subsection, the
21 term ‘part B rebatable drug’ means a single
22 source drug or biological (as defined in sub-
23 paragraph (D) of subsection (c)(6)), including a
24 biosimilar biological product (as defined in sub-
25 paragraph (H) of such subsection) but exclud-

1 ing a qualifying biosimilar biological product
2 (as defined in subsection (b)(8)(B)(iii)), that
3 would be payable under this part if such drug
4 were furnished to an individual enrolled under
5 this part, except such term shall not include
6 such a drug or biological—

7 “(i) if, as determined by the Sec-
8 retary, the average total allowed charges
9 for such drug or biological under this part
10 for a year per individual that uses such a
11 drug or biological are less than, subject to
12 subparagraph (B), \$100; or

13 “(ii) that is a vaccine described in
14 subparagraph (A) or (B) of section
15 1861(s)(10).

16 “(B) INCREASE.—The dollar amount ap-
17 plied under subparagraph (A)(i)—

18 “(i) for 2024, shall be the dollar
19 amount specified under such subparagraph
20 for 2023, increased by the percentage in-
21 crease in the consumer price index for all
22 urban consumers (United States city aver-
23 age) for the 12-month period ending with
24 June of the previous year; and

1 “(ii) for a subsequent year, shall be
2 the dollar amount specified in this clause
3 (or clause (i)) for the previous year (with-
4 out application of subparagraph (C)), in-
5 creased by the percentage increase in the
6 consumer price index for all urban con-
7 sumers (United States city average) for
8 the 12-month period ending with June of
9 the previous year.

10 “(C) ROUNDING.—Any dollar amount de-
11 termined under subparagraph (B) that is not a
12 multiple of \$10 shall be rounded to the nearest
13 multiple of \$10.

14 “(3) REBATE AMOUNT.—

15 “(A) IN GENERAL.—For purposes of para-
16 graph (1), the amount specified in this para-
17 graph for a part B rebatable drug assigned to
18 a billing and payment code for a calendar quar-
19 ter is, subject to subparagraphs (B) and (G)
20 and paragraph (4), the amount equal to the
21 product of—

22 “(i) the total number of billing units
23 determined under subparagraph (B) for
24 the billing and payment code of such drug;
25 and

1 “(ii) the amount (if any) by which—

2 “(I) the amount equal to—

3 “(aa) in the case of a part B
4 rebatable drug described in para-
5 graph (1)(B) of section
6 1847A(b), 106 percent of the
7 amount determined under para-
8 graph (4) of such section for
9 such drug during the calendar
10 quarter; or

11 “(bb) in the case of a part B
12 rebatable drug described in para-
13 graph (1)(C) of such section, the
14 payment amount under such
15 paragraph for such drug during
16 the calendar quarter; exceeds

17 “(II) the inflation-adjusted pay-
18 ment amount determined under sub-
19 paragraph (C) for such part B
20 rebatable drug during the calendar
21 quarter.

22 “(B) TOTAL NUMBER OF BILLING
23 UNITS.—For purposes of subparagraph (A)(i),
24 the total number of billing units with respect to

1 a part B rebatable drug is determined as fol-
2 lows:

3 “(i) Determine the total number of
4 units equal to—

5 “(I) the total number of units, as
6 reported under subsection (c)(1)(B)
7 for each National Drug Code of such
8 drug during the calendar quarter that
9 is two calendar quarters prior to the
10 calendar quarter as described in sub-
11 paragraph (A), minus

12 “(II) the total number of units
13 with respect to each National Drug
14 Code of such drug for which payment
15 was made under a State plan under
16 title XIX (or waiver of such plan), as
17 reported by States under section
18 1927(b)(2)(A) for the rebate period
19 that is the same calendar quarter as
20 described in subclause (I).

21 “(ii) Convert the units determined
22 under clause (i) to billing units for the bill-
23 ing and payment code of such drug, using
24 a methodology similar to the methodology
25 used under this section, by dividing the

1 units determined under clause (i) for each
 2 National Drug Code of such drug by the
 3 billing unit for the billing and payment
 4 code of such drug.

5 “(iii) Compute the sum of the billing
 6 units for each National Drug Code of such
 7 drug in clause (ii).

8 “(C) DETERMINATION OF INFLATION-AD-
 9 JUSTED PAYMENT AMOUNT.—The inflation-ad-
 10 justed payment amount determined under this
 11 subparagraph for a part B rebatable drug for
 12 a calendar quarter is—

13 “(i) the payment amount for the bill-
 14 ing and payment code for such drug in the
 15 payment amount benchmark quarter (as
 16 defined in subparagraph (D)); increased by

17 “(ii) the percentage by which the re-
 18 bate period CPI–U (as defined in subpara-
 19 graph (F)) for the calendar quarter ex-
 20 ceeds the benchmark period CPI–U (as de-
 21 fined in subparagraph (E)).

22 “(D) PAYMENT AMOUNT BENCHMARK
 23 QUARTER.—The term ‘payment amount bench-
 24 mark quarter’ means the calendar quarter im-

1 mediately prior to the calendar quarter begin-
2 ning October 1, 2021.

3 “(E) BENCHMARK PERIOD CPI-U.—The
4 term ‘benchmark period CPI-U’ means the con-
5 sumer price index for all urban consumers
6 (United States city average) for the last month
7 of the calendar quarter beginning October 1,
8 2021.

9 “(F) REBATE PERIOD CPI-U.—The term
10 ‘rebate period CPI-U’ means, with respect to a
11 calendar quarter described in subparagraph
12 (C), the greater of the benchmark period CPI-
13 U and the consumer price index for all urban
14 consumers (United States city average) for the
15 first month of the calendar quarter that is two
16 calendar quarters prior to such described cal-
17 endar quarter.

18 “(G) EXEMPTION FOR SHORTAGES AND
19 SEVERE SUPPLY CHAIN DISRUPTIONS.—The
20 Secretary shall reduce or waive the amount
21 under subparagraph (A) with respect to a part
22 B rebatable drug that is described as currently
23 in shortage on the shortage list in effect under
24 section 506E of the Federal Food, Drug, and
25 Cosmetic Act or in the case of a biosimilar bio-

1 logical product, when the Secretary determines
2 there are severe supply chain disruptions.

3 “(4) SPECIAL TREATMENT OF CERTAIN DRUGS
4 AND EXEMPTION.—

5 “(A) SUBSEQUENTLY APPROVED DRUGS.—

6 In the case of a part B rebatable drug first ap-
7 proved or licensed by the Food and Drug Ad-
8 ministration after March 1, 2021, clause (i) of
9 paragraph (3)(C) shall be applied as if the term
10 ‘payment amount benchmark quarter’ were de-
11 fined under paragraph (3)(D) as the third full
12 calendar quarter after the day on which the
13 drug was first marketed and clause (ii) of para-
14 graph (3)(C) shall be applied as if the term
15 ‘benchmark period CPI-U’ were defined under
16 paragraph (3)(E) as if the reference to ‘the last
17 month of the calendar quarter immediately
18 prior to the calendar quarter beginning October
19 1, 2021’ under such paragraph were a reference
20 to ‘the first month of the first full calendar
21 quarter after the day on which the drug was
22 first marketed’.

23 “(B) TIMELINE FOR PROVISION OF RE-
24 BATES FOR SUBSEQUENTLY APPROVED
25 DRUGS.—In the case of a part B rebatable drug

1 first approved or licensed by the Food and
2 Drug Administration after March 1, 2021,
3 paragraph (1)(B) shall be applied as if the ref-
4 erence to ‘July 1, 2023’ under such paragraph
5 were a reference to the later of the 6th full cal-
6 endar quarter after the day on which the drug
7 was first marketed or July 1, 2023.

8 “(C) SELECTED DRUGS.—In the case of a
9 part B rebatable drug that is a selected drug
10 (as defined in section 1192(c)) for a price appli-
11 cability period (as defined in section
12 1191(b)(2)), in the case such drug is deter-
13 mined (pursuant to such section 1192(c)) to no
14 longer be a selected drug, beginning the first
15 calendar quarter after the price applicability pe-
16 riod with respect to such drug, clause (i) of
17 paragraph (3)(C) shall be applied as if the term
18 ‘payment amount benchmark quarter’ were de-
19 fined under paragraph (3)(D) as the calendar
20 quarter beginning January 1 of the last year
21 beginning during such price applicability period
22 with respect to such selected drug and clause
23 (ii) of paragraph (3)(C) shall be applied as if
24 the term ‘benchmark period CPI–U’ were de-
25 fined under paragraph (3)(E) as if the ref-

1 erence to ‘the last month of the calendar quar-
2 ter immediately prior to the calendar quarter
3 beginning October 1, 2021’ under such para-
4 graph were a reference to the March of the year
5 preceding such last year.

6 “(5) APPLICATION TO BENEFICIARY COINSUR-
7 ANCE.—In the case of a part B rebatable drug, if
8 the payment amount described in paragraph
9 (3)(A)(ii)(I) (or, in the case of a part B rebatable
10 drug that is a selected drug (as defined in section
11 1192(c)), the payment amount described in sub-
12 section (b)(1)(B) for such drug) for a calendar quar-
13 ter exceeds the inflation adjusted payment for such
14 quarter—

15 “(A) in computing the amount of any coin-
16 surance applicable under this part to an indi-
17 vidual to whom such drug is furnished, the
18 computation of such coinsurance shall be equal
19 to 20 percent of the inflation-adjusted payment
20 amount determined under paragraph (3)(C) for
21 such part B rebatable drug; and

22 “(B) the amount of such coinsurance for
23 such calendar quarter, as computed under sub-
24 paragraph (A), shall be applied as a percent, as
25 determined by the Secretary, to the payment

1 amount that would otherwise apply under sub-
2 paragraph (B) or (C) of subsection (b)(1).

3 “(6) REBATE DEPOSITS.—Amounts paid as re-
4 bates under paragraph (1)(B) shall be deposited into
5 the Federal Supplementary Medical Insurance Trust
6 Fund established under section 1841.

7 “(7) CIVIL MONEY PENALTY.—If a manufac-
8 turer of a part B rebatable drug has failed to com-
9 ply with the requirements under paragraph (1)(B)
10 for such drug for a calendar quarter, the manufac-
11 turer shall be subject to, in accordance with a proc-
12 ess established by the Secretary pursuant to regula-
13 tions, a civil money penalty in an amount equal to
14 at least 125 percent of the amount specified in para-
15 graph (3) for such drug for such calendar quarter.
16 The provisions of section 1128A (other than sub-
17 sections (a) (with respect to amounts of penalties or
18 additional assessments) and (b)) shall apply to a
19 civil money penalty under this paragraph in the
20 same manner as such provisions apply to a penalty
21 or proceeding under section 1128A(a).”; and

22 (2) in subsection (i), as redesignated by para-
23 graph (1)—

24 (A) in paragraph (4), by striking at the
25 end “and”;

1 (B) in paragraph (5), by striking at the
2 end the period and inserting a semicolon; and

3 (C) by adding at the end the following new
4 paragraphs:

5 “(6) the determination of units under sub-
6 section (h);

7 “(7) the determination of whether a drug is a
8 part B rebatable drug under subsection (h);

9 “(8) the calculation of the rebate amount under
10 subsection (h);

11 “(9) the computation of coinsurance under sub-
12 section (h)(5); and

13 “(10) the computation of amounts paid under
14 section 1833(a)(1)(EE).”.

15 (b) AMOUNTS PAYABLE; COST-SHARING.—Section
16 1833 of the Social Security Act (42 U.S.C. 1395l) is
17 amended—

18 (1) in subsection (a)(1)—

19 (A) in subparagraph (G), by inserting “,
20 subject to subsection (i)(9),” after “the
21 amounts paid”;

22 (B) in subparagraph (S), by striking “with
23 respect to” and inserting “subject to subpara-
24 graph (EE), with respect to”;

1 (C) by striking “and (DD)” and inserting
2 “(DD)”; and

3 (D) by inserting before the semicolon at
4 the end the following: “, and (EE) with respect
5 to a part B rebatable drug (as defined in para-
6 graph (2) of section 1847A(h)) for which the
7 payment amount for a calendar quarter under
8 paragraph (3)(A)(ii)(I) of such section (or, in
9 the case of a part B rebatable drug that is a
10 selected drug (as defined in section 1192(c)) for
11 which, the payment amount described in section
12 1847A(b)(1)(B)) for such drug for such quarter
13 exceeds the inflation-adjusted payment under
14 paragraph (3)(A)(ii)(II) of such section for
15 such quarter, the amounts paid shall be equal
16 to the percent of the payment amount under
17 paragraph (3)(A)(ii)(I) of such section or sec-
18 tion 1847A(b)(1)(B), as applicable, that equals
19 the difference between (i) 100 percent, and (ii)
20 the percent applied under section
21 1847A(h)(5)(B)”;

22 (2) in subsection (i), by adding at the end the
23 following new paragraph:

24 “(9) In the case of a part B rebatable drug (as de-
25 fined in paragraph (2) of section 1847A(h)) for which pay-

1 ment under this subsection is not packaged into a payment
 2 for a service furnished on or after July 1, 2023, under
 3 the revised payment system under this subsection, in lieu
 4 of calculation of coinsurance and the amount of payment
 5 otherwise applicable under this subsection, the provisions
 6 of section 1847A(h)(5) and paragraph (1)(EE) of sub-
 7 section (a), shall, as determined appropriate by the Sec-
 8 retary, apply under this subsection in the same manner
 9 as such provisions of section 1847A(h)(5) and subsection
 10 (a) apply under such section and subsection.”; and

11 (3) in subsection (t)(8), by adding at the end
 12 the following new subparagraph:

13 “(F) PART B REBATABLE DRUGS.—In the
 14 case of a part B rebatable drug (as defined in
 15 paragraph (2) of section 1847A(h), except if
 16 such drug does not have a copayment amount
 17 as a result of application of subparagraph (E))
 18 for which payment under this part is not pack-
 19 aged into a payment for a covered OPD service
 20 (or group of services) furnished on or after July
 21 1, 2023, and the payment for such drug under
 22 this subsection is the same as the amount for
 23 a calendar quarter under paragraph
 24 (3)(A)(ii)(I) of section 1847A(h), under the sys-
 25 tem under this subsection, in lieu of calculation

1 of the copayment amount and the amount of
 2 payment otherwise applicable under this sub-
 3 section (other than the application of the limita-
 4 tion described in subparagraph (C)), the provi-
 5 sions of section 1847A(h)(5) and paragraph
 6 (1)(EE) of subsection (a), shall, as determined
 7 appropriate by the Secretary, apply under this
 8 subsection in the same manner as such provi-
 9 sions of section 1847A(h)(5) and subsection (a)
 10 apply under such section and subsection.”.

11 (c) CONFORMING AMENDMENTS.—

12 (1) TO PART B ASP CALCULATION.—Section
 13 1847A(c)(3) of the Social Security Act (42 U.S.C.
 14 1395w–3a(c)(3)) is amended by inserting “sub-
 15 section (h) or” before “section 1927”.

16 (2) EXCLUDING PART B DRUG INFLATION RE-
 17 BATE FROM BEST PRICE.—Section
 18 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
 19 U.S.C. 1396r–8(c)(1)(C)(ii)(I)) is amended by in-
 20 serting “or section 1847A(h)” after “this section”.

21 (3) COORDINATION WITH MEDICAID REBATE IN-
 22 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
 23 of the Social Security Act (42 U.S.C. 1396r–
 24 8(b)(3)(D)(i)) is amended by inserting “and the re-
 25 bate” after “the payment amount”.

1 (4) EXCLUDING PART B DRUG INFLATION RE-
 2 BATES FROM AVERAGE MANUFACTURER PRICE.—
 3 Section 1927(k)(1)(B)(i) of the Social Security Act
 4 (42 U.S.C. 1396r–8(k)(1)(B)(i)), as previously
 5 amended, is further amended—

6 (A) in subclause (IV), by striking “and”;

7 (B) in subclause (V), by striking the period
 8 at the end and inserting a semicolon; and

9 (C) by adding at the end the following new
 10 subclause:

11 “(VI) rebates paid by manufac-
 12 turers under section 1847A(h); and”.

13 (d) FUNDING.—In addition to amounts otherwise
 14 available, there are appropriated to the Centers for Medi-
 15 care & Medicaid Services, out of any money in the Treas-
 16 ury not otherwise appropriated, \$12,500,000 for fiscal
 17 year 2022 and \$7,500,000 for each of fiscal years 2023
 18 through 2031, to remain available until expended, to carry
 19 out the provisions of, including the amendments made by,
 20 this section.

21 **SEC. 202. MEDICARE PART D REBATE BY MANUFACTURERS.**

22 (a) IN GENERAL.—Part D of title XVIII of the Social
 23 Security Act is amended by inserting after section 1860D–
 24 14A (42 U.S.C. 1395w–114a) the following new section:

1 **“SEC. 1860D–14B. MANUFACTURER REBATE FOR CERTAIN**
2 **DRUGS WITH PRICES INCREASING FASTER**
3 **THAN INFLATION.**

4 “(a) REQUIREMENTS.—

5 “(1) SECRETARIAL PROVISION OF INFORMA-
6 TION.—Not later than 9 months after the end of
7 each applicable year (as defined in subsection
8 (g)(7)), subject to paragraph (3), the Secretary
9 shall, for each part D rebatable drug, report to each
10 manufacturer of such part D rebatable drug the fol-
11 lowing for such year:

12 “(A) The amount (if any) of the excess an-
13 nual manufacturer price increase described in
14 subsection (b)(1)(A)(ii) for each dosage form
15 and strength with respect to such drug and
16 year.

17 “(B) The rebate amount specified under
18 subsection (b) for each dosage form and
19 strength with respect to such drug and year.

20 “(2) MANUFACTURER REQUIREMENTS.—For
21 each applicable year, the manufacturer of a part D
22 rebatable drug, for each dosage form and strength
23 with respect to such drug, not later than 30 days
24 after the date of receipt from the Secretary of the
25 information described in paragraph (1) for such
26 year, shall provide to the Secretary a rebate that is

1 equal to the amount specified in subsection (b) for
2 such dosage form and strength with respect to such
3 drug for such year.

4 “(3) TRANSITION RULE FOR REPORTING.—The
5 Secretary may, for each rebatable covered part D
6 drug, delay the timeframe for reporting the informa-
7 tion and rebate amount described in subparagraphs
8 (A) and (B) of such paragraph for the applicable
9 year of 2023 until not later than September 30,
10 2025.

11 “(b) REBATE AMOUNT.—

12 “(1) IN GENERAL.—

13 “(A) CALCULATION.—For purposes of this
14 section, the amount specified in this subsection
15 for a dosage form and strength with respect to
16 a part D rebatable drug and applicable year is,
17 subject to subparagraph (C), paragraph (5)(B),
18 and paragraph (6), the amount equal to the
19 product of—

20 “(i) subject to subparagraph (B) of
21 this paragraph, the total number of units
22 that are used to calculate the average man-
23 ufacturer price of such dosage form and
24 strength with respect to such part D
25 rebatable drug, as reported by the manu-

1 facturer of such drug under section 1927
2 for each month, with respect to such year;
3 and

4 “(ii) the amount (if any) by which—

5 “(I) the annual manufacturer
6 price (as determined in paragraph
7 (2)) paid for such dosage form and
8 strength with respect to such part D
9 rebatable drug for the year; exceeds

10 “(II) the inflation-adjusted pay-
11 ment amount determined under para-
12 graph (3) for such dosage form and
13 strength with respect to such part D
14 rebatable drug for the year.

15 “(B) EXCLUDED UNITS.—For purposes of
16 subparagraph (A)(i), the Secretary shall exclude
17 from the total number of units for a dosage
18 form and strength with respect to a part D
19 rebatable drug, with respect to an applicable
20 year, the following:

21 “(i) Units of each dosage form and
22 strength of such part D rebatable drug for
23 which payment was made under a State
24 plan under title XIX (or waiver of such

1 plan), as reported by States under section
2 1927(b)(2)(A).

3 “(ii) Units of each dosage form and
4 strength of such part D rebatable drug for
5 which a rebate is paid under section
6 1847A(h).

7 “(C) EXEMPTION FOR SHORTAGES AND
8 SEVERE SUPPLY CHAIN DISRUPTIONS.—The
9 Secretary shall reduce or waive the amount
10 under subparagraph (A) with respect to a part
11 D rebatable drug that is described as currently
12 in shortage on the shortage list in effect under
13 section 506E of the Federal Food, Drug, and
14 Cosmetic Act or in the case of a generic drug,
15 when the Secretary determines there are severe
16 supply chain disruptions.

17 “(2) DETERMINATION OF ANNUAL MANUFAC-
18 Turer PRICE.—The annual manufacturer price de-
19 termined under this paragraph for a dosage form
20 and strength, with respect to a part D rebatable
21 drug and an applicable year, is the sum of the prod-
22 ucts of—

23 “(A) the average manufacturer price (as
24 defined in subsection (g)(6)) of such dosage
25 form and strength, as calculated for a unit of

1 such drug, with respect to each of the calendar
2 quarters of such year; and

3 “(B) the ratio of—

4 “(i) the total number of units of such
5 dosage form and strength reported under
6 section 1927 with respect to each such cal-
7 endar quarter of such year; to

8 “(ii) the total number of units of such
9 dosage form and strength reported under
10 section 1927 with respect to such year, as
11 determined by the Secretary.

12 “(3) DETERMINATION OF INFLATION-ADJUSTED
13 PAYMENT AMOUNT.—The inflation-adjusted payment
14 amount determined under this paragraph for a dos-
15 age form and strength with respect to a part D
16 rebatable drug for an applicable year, subject to
17 paragraph (5), is—

18 “(A) the benchmark year manufacturer
19 price determined under paragraph (4) for such
20 dosage form and strength with respect to such
21 drug and year; increased by

22 “(B) the percentage by which the applica-
23 ble year CPI–U (as defined in subsection
24 (g)(5)) for the year exceeds the benchmark pe-
25 riod CPI–U (as defined in subsection (g)(4)).

1 “(4) DETERMINATION OF BENCHMARK YEAR
2 MANUFACTURER PRICE.—The benchmark year man-
3 ufacturer price determined under this paragraph for
4 a dosage form and strength, with respect to a part
5 D rebatable drug and an applicable year, is the sum
6 of the products of—

7 “(A) the average manufacturer price (as
8 defined in subsection (g)(6)) of such dosage
9 form and strength, as calculated for a unit of
10 such drug, with respect to each of the calendar
11 quarters of the payment amount benchmark
12 year (as defined in subsection (g)(3)); and

13 “(B) the ratio of—

14 “(i) the total number of units re-
15 ported under section 1927 of such dosage
16 form and strength with respect to each
17 such calendar quarter of such payment
18 amount benchmark year; to

19 “(ii) the total number of units re-
20 ported under section 1927 of such dosage
21 form and strength with respect to such
22 payment amount benchmark year.

23 “(5) SPECIAL TREATMENT OF CERTAIN DRUGS
24 AND EXEMPTION.—

“(A) SUBSEQUENTLY APPROVED DRUGS.—

In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after October 1, 2021, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term ‘payment amount benchmark year’ were defined under subsection (g)(3) as the first calendar year beginning after the day on which the drug was first marketed by any manufacturer and subparagraph (B) of paragraph (3) shall be applied as if the term ‘benchmark period CPI-U’ were defined under subsection (g)(4) as if the reference to ‘the month immediately prior to October 2021’ under such subsection were a reference to ‘January of the first year beginning after the date on which the drug was first marketed by any manufacturer’.

“(B) TREATMENT OF NEW FORMULATIONS.—

“(i) IN GENERAL.—In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the re-

1 bate amount under paragraph (1) and the
2 inflation adjusted payment amount under
3 paragraph (3) with respect to such part D
4 rebatable drug and an applicable year, con-
5 sistent with the formula applied under sub-
6 section (c)(2)(C) of section 1927 for deter-
7 mining a rebate obligation for a rebate pe-
8 riod under such section.

9 “(ii) LINE EXTENSION DEFINED.—In
10 this subparagraph, the term ‘line exten-
11 sion’ means, with respect to a part D
12 rebatable drug, a new formulation of the
13 drug, such as an extended release formula-
14 tion, but does not include an abuse-deter-
15 rent formulation of the drug (as deter-
16 mined by the Secretary), regardless of
17 whether such abuse-deterrent formulation
18 is an extended release formulation.

19 “(C) SELECTED DRUGS.—In the case of a
20 part D rebateable drug that is a selected drug
21 (as defined in section 1192(c)) for a price appli-
22 cability period (as defined in section
23 1191(b)(2)), in the case such drug is deter-
24 mined (pursuant to such section 1192(c)) to no
25 longer be a selected drug, for each applicable

1 year beginning after the price applicability pe-
2 riod with respect to such drug, subparagraphs
3 (A) and (B) of paragraph (4) shall be applied
4 as if the term ‘payment amount benchmark
5 year’ were defined under subsection (g)(3) as
6 the last year beginning during such price appli-
7 cability period with respect to such selected
8 drug and subparagraph (B) of paragraph (3)
9 shall be applied as if the term ‘benchmark pe-
10 riod CPI-U’ were defined under subsection
11 (g)(4) as if the reference to ‘the month imme-
12 diately prior to October 1, 2021’ under such
13 subsection were a reference to January of the
14 last year beginning during such price applica-
15 bility period with respect to such drug.

16 “(6) RECONCILIATION IN CASE OF REVISED
17 AMP REPORTS.—The Secretary shall provide for a
18 method and process under which, in the case of a
19 manufacturer of a part D rebatable drug that sub-
20 mits revisions to information submitted under sec-
21 tion 1927 by the manufacturer with respect to such
22 drug, the Secretary determines, pursuant to such re-
23 visions, adjustments, if any, to the calculation of the
24 amount specified in this subsection for a dosage
25 form and strength with respect to such part D

1 rebatable drug and an applicable year and reconciles
2 any overpayments or underpayments in amounts
3 paid as rebates under this subsection. Any identified
4 underpayment shall be rectified by the manufacturer
5 not later than 30 days after the date of receipt from
6 the Secretary of information on such underpayment.

7 “(c) REBATE DEPOSITS.—Amounts paid as rebates
8 under subsection (b) shall be deposited into the Medicare
9 Prescription Drug Account in the Federal Supplementary
10 Medical Insurance Trust Fund established under section
11 1841.

12 “(d) INFORMATION.—For purposes of carrying out
13 this section, the Secretary shall use information submitted
14 by manufacturers under section 1927(b)(3) and informa-
15 tion submitted by States under section 1927(b)(2)(A).

16 “(e) CIVIL MONEY PENALTY.—If a manufacturer of
17 a part D rebatable drug has failed to comply with the re-
18 quirement under subsection (a)(2) with respect to such
19 drug for an applicable year, the manufacturer shall be
20 subject to, in accordance with a process established by the
21 Secretary pursuant to regulations, a civil money penalty
22 in an amount equal to 125 percent of the amount specified
23 in subsection (b) for such drug for such year. The provi-
24 sions of section 1128A (other than subsections (a) (with
25 respect to amounts of penalties or additional assessments)

1 and (b)) shall apply to a civil money penalty under this
 2 subsection in the same manner as such provisions apply
 3 to a penalty or proceeding under section 1128A(a).

4 “(f) NO ADMINISTRATIVE OR JUDICIAL REVIEW.—
 5 There shall be no administrative or judicial review of the
 6 following:

7 “(1) The determination of units under this sec-
 8 tion.

9 “(2) The determination of whether a drug is a
 10 part D rebatable drug under this section.

11 “(3) The calculation of the rebate amount
 12 under this section.

13 “(g) DEFINITIONS.—In this section:

14 “(1) PART D REBATABLE DRUG.—

15 “(A) IN GENERAL.—The term ‘part D
 16 rebatable drug’ means a drug or biological that
 17 would (without application of this section) be a
 18 covered part D drug, except such term shall,
 19 with respect to an applicable year, not include
 20 such a drug or biological if the average annual
 21 total cost under this part for such year per in-
 22 dividual who uses such a drug or biological, as
 23 determined by the Secretary, is less than, sub-
 24 ject to subparagraph (B), \$100, as determined
 25 by the Secretary using the most recent data

1 available or, if data is not available, as esti-
2 mated by the Secretary.

3 “(B) INCREASE.—The dollar amount ap-
4 plied under subparagraph (A)—

5 “(i) for 2024, shall be the dollar
6 amount specified under such subparagraph
7 for 2023, increased by the percentage in-
8 crease in the consumer price index for all
9 urban consumers (United States city aver-
10 age) for the 12-month period beginning
11 with January of 2023; and

12 “(ii) for a subsequent year, shall be
13 the dollar amount specified in this sub-
14 paragraph for the previous year, increased
15 by the percentage increase in the consumer
16 price index for all urban consumers
17 (United States city average) for the 12-
18 month period beginning with January of
19 the previous year.

20 Any dollar amount specified under this sub-
21 paragraph that is not a multiple of \$10 shall be
22 rounded to the nearest multiple of \$10.

23 “(2) UNIT.—The term ‘unit’ means, with re-
24 spect to a part D rebatable drug, the lowest dispen-
25 sable amount (such as a capsule or tablet, milligram

1 of molecules, or grams) of the part D rebatable
2 drug, as reported under section 1927.

3 “(3) PAYMENT AMOUNT BENCHMARK YEAR.—
4 The term ‘payment amount benchmark year’ means
5 the year ending in the month immediately prior to
6 October 1, 2021.

7 “(4) BENCHMARK PERIOD CPI–U.—The term
8 ‘benchmark period CPI–U’ means the consumer
9 price index for all urban consumers (United States
10 city average) for the month immediately prior to Oc-
11 tober 2021.

12 “(5) APPLICABLE YEAR CPI–U.—The term ‘ap-
13 plicable year CPI–U’ means, with respect to an ap-
14 plicable year, the consumer price index for all urban
15 consumers (United States city average) for January
16 of such year.

17 “(6) AVERAGE MANUFACTURER PRICE.—The
18 term ‘average manufacturer price’ has the meaning,
19 with respect to a part D rebatable drug of a manu-
20 facturer, given such term in section 1927(k)(1), with
21 respect to a covered outpatient drug of a manufac-
22 turer for a rebate period under section 1927.

23 “(7) APPLICABLE YEAR.—The term ‘applicable
24 year’ means a calendar year beginning with 2023.

1 “(h) IMPLEMENTATION FOR 2023 AND 2024.—Not-
 2 withstanding any other provision of this section, the Sec-
 3 retary shall implement this section for 2023 and 2024 by
 4 program instruction or otherwise.”.

5 (b) CONFORMING AMENDMENTS.—

6 (1) TO PART B ASP CALCULATION.—Section
 7 1847A(c)(3) of the Social Security Act (42 U.S.C.
 8 1395w–3a(c)(3)), as amended by section 201(c)(1),
 9 is further amended by striking “subsection (h) or
 10 section 1927” and inserting “subsection (h), section
 11 1927, or section 1860D–14B”.

12 (2) EXCLUDING PART D DRUG INFLATION RE-
 13 BATE FROM BEST PRICE.—Section
 14 1927(c)(1)(C)(ii)(I) of the Social Security Act (42
 15 U.S.C. 1396r–8(c)(1)(C)(ii)(I)), as amended by sec-
 16 tion 201(c)(2), is further amended by striking “or
 17 section 1847A(h)” and inserting “, section
 18 1847A(h), or section 1860D–14B”.

19 (3) COORDINATION WITH MEDICAID REBATE IN-
 20 FORMATION DISCLOSURE.—Section 1927(b)(3)(D)(i)
 21 of the Social Security Act (42 U.S.C. 1396r–
 22 8(b)(3)(D)(i)), as amended by section 201(c)(3), is
 23 further amended by striking “or to carry out section
 24 1847B” and inserting “or to carry out section
 25 1847B or section 1860D–14B”.

1 (4) EXCLUDING PART D DRUG INFLATION RE-
 2 BATES FROM AVERAGE MANUFACTURER PRICE.—
 3 Section 1927(k)(1)(B)(i) of the Social Security Act
 4 (42 U.S.C. 1396r–8(k)(1)(B)(i)), as previously
 5 amended, is further amended by adding at the end
 6 the following new subclause:

7 “(VII) rebates paid by manufac-
 8 turers under section 1860D–14B.”.

9 (c) FUNDING.—In addition to amounts otherwise
 10 available, there are appropriated to the Centers for Medi-
 11 care & Medicaid Services, out of any money in the Treas-
 12 ury not otherwise appropriated, \$12,500,000 for fiscal
 13 year 2022 and \$7,500,000 for each of fiscal years 2023
 14 through 2031, to remain available until expended, to carry
 15 out the provisions of, including the amendments made by,
 16 this section.

17 **TITLE III—PART D IMPROVE-**
 18 **MENTS AND MAXIMUM OUT-**
 19 **OF-POCKET CAP FOR MEDI-**
 20 **CARE BENEFICIARIES**

21 **SEC. 301. MEDICARE PART D BENEFIT REDESIGN.**

22 (a) BENEFIT STRUCTURE REDESIGN.—Section
 23 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
 24 102(b)) is amended—

25 (1) in paragraph (2)—

1 (A) in subparagraph (A), in the matter
 2 preceding clause (i), by inserting “for a year
 3 preceding 2024 and for costs above the annual
 4 deductible specified in paragraph (1) and up to
 5 the annual out-of-pocket threshold specified in
 6 paragraph (4)(B) for 2024 and each subsequent
 7 year” after “paragraph (3)”;

8 (B) in subparagraph (C)—

9 (i) in clause (i), in the matter pre-
 10 ceding subclause (I), by inserting “for a
 11 year preceding 2024,” after “paragraph
 12 (4),”; and

13 (ii) in clause (ii)(III), by striking
 14 “and each subsequent year” and inserting
 15 “through 2023”; and

16 (C) in subparagraph (D)—

17 (i) in clause (i)—

18 (I) in the matter preceding sub-
 19 clause (I), by inserting “for a year
 20 preceding 2024,” after “paragraph
 21 (4),”; and

22 (II) in subclause (I)(bb), by
 23 striking “a year after 2018” and in-
 24 serting “each of years 2019 through
 25 2023”; and

1 (ii) in clause (ii)(V), by striking
2 “2019 and each subsequent year” and in-
3 serting “each of years 2019 through
4 2023”;

5 (2) in paragraph (3)(A)—

6 (A) in the matter preceding clause (i), by
7 inserting “for a year preceding 2024,” after
8 “and (4),”; and

9 (B) in clause (ii), by striking “for a subse-
10 quent year” and inserting “for each of years
11 2007 through 2023”; and

12 (3) in paragraph (4)—

13 (A) in subparagraph (A)—

14 (i) in clause (i)—

15 (I) by redesignating subclauses
16 (I) and (II) as items (aa) and (bb),
17 respectively, and moving the margin
18 of each such redesignated item 2 ems
19 to the right;

20 (II) in the matter preceding item
21 (aa), as redesignated by subclause (I),
22 by striking “is equal to the greater
23 of—” and inserting “is equal to—

24 “(I) for a year preceding 2024,
25 the greater of—”;

1 (III) by striking the period at the
 2 end of item (bb), as redesignated by
 3 subclause (I), and inserting “; and”;
 4 and

5 (IV) by adding at the end the fol-
 6 lowing:

7 “(II) for 2024 and each suc-
 8 ceeding year, \$0.”; and
 9 (ii) in clause (ii)—

10 (I) by striking “clause (i)(I)” and
 11 inserting “clause (i)(I)(aa)”;

12 (II) by adding at the end the fol-
 13 lowing new sentence: “The Secretary
 14 shall continue to calculate the dollar
 15 amounts specified in clause (i)(I)(aa),
 16 including with the adjustment under
 17 this clause, after 2023 for purposes of
 18 section 1860D–14(a)(1)(D)(iii).”;

19 (B) in subparagraph (B)—

20 (i) in clause (i)—

21 (I) in subclause (V), by striking
 22 “or” at the end;

23 (II) in subclause (VI)—

24 (aa) by striking “for a sub-
 25 sequent year” and inserting “for

1 each of years 2021 through
2 2023”; and

3 (bb) by striking the period
4 at the end and inserting a semi-
5 colon; and

6 (III) by adding at the end the
7 following new subclauses:

8 “(VII) for 2024, is equal to
9 \$2,000; or

10 “(VIII) for a subsequent year, is
11 equal to the amount specified in this
12 subparagraph for the previous year,
13 increased by the annual percentage in-
14 crease described in paragraph (6) for
15 the year involved.”; and

16 (ii) in clause (ii), by striking “clause
17 (i)(II)” and inserting “clause (i)”;

18 (C) in subparagraph (C)(i), by striking
19 “and for amounts” and inserting “and, for a
20 year preceding 2024, for amounts”; and

21 (D) in subparagraph (E), by striking “In
22 applying” and inserting “For each of years
23 2011 through 2023, in applying”.

1 (b) REINSURANCE PAYMENT AMOUNT.—Section
2 1860D–15(b) of the Social Security Act (42 U.S.C.
3 1395w–115(b)) is amended—

4 (1) in paragraph (1)—

5 (A) by striking “equal to 80 percent” and
6 inserting “equal to—

7 “(A) for a year preceding 2024, 80 per-
8 cent”;

9 (B) in subparagraph (A), as added by sub-
10 paragraph (A), by striking the period at the
11 end and inserting “; and”; and

12 (C) by adding at the end the following new
13 subparagraph:

14 “(B) for 2024 and each subsequent year,
15 the sum of—

16 “(i) an amount equal to 20 percent of
17 such allowable reinsurance costs attrib-
18 utable to that portion of gross prescription
19 drug costs as specified in paragraph (3) in-
20 curred in the coverage year after such indi-
21 vidual has incurred costs that exceed the
22 annual out-of-pocket threshold specified in
23 section 1860D–2(b)(4)(B) with respect to
24 applicable drugs (as defined in section
25 1860D–14C(g)(2)); and

1 “(ii) an amount equal to 40 percent of
 2 such allowable reinsurance costs attrib-
 3 utable to that portion of gross prescription
 4 drug costs as specified in paragraph (3) in-
 5 curred in the coverage year after such indi-
 6 vidual has incurred costs that exceed the
 7 annual out-of-pocket threshold specified in
 8 section 1860D–2(b)(4)(B) with respect to
 9 covered part D drugs that are not applica-
 10 ble drugs (as so defined).”;

11 (2) in paragraph (2)—

12 (A) by striking “COSTS.—For purposes”
 13 and inserting “COSTS.—

14 “(A) IN GENERAL.—Subject to subpara-
 15 graph (B), for purposes”; and

16 (B) by adding at the end the following new
 17 subparagraph:

18 “(B) INCLUSION OF MANUFACTURER DIS-
 19 COUNTS ON APPLICABLE DRUGS.—For purposes
 20 of applying subparagraph (A), the term ‘allow-
 21 able reinsurance costs’ shall include the portion
 22 of the negotiated price (as defined in section
 23 1860D–14C(g)(6)) of an applicable drug (as
 24 defined in section 1860D–14C(g)(2)) that was
 25 paid by a manufacturer under the manufacturer

1 discount program under section 1860D–14C.”;

2 and

3 (3) in paragraph (3)—

4 (A) in the first sentence, by striking “For
5 purposes” and inserting “Subject to paragraph
6 (2)(B), for purposes”; and

7 (B) in the second sentence, by inserting
8 “(or, with respect to 2024 and subsequent
9 years, in the case of an applicable drug, as de-
10 fined in section 1860D–14C(g)(2), by a manu-
11 facturer)” after “by the individual or under the
12 plan”.

13 (c) REDUCED COST-SHARING; BENEFICIARY PRE-
14 MIUM PERCENTAGE.—

15 (1) COST-SHARING.—

16 (A) IN GENERAL.—Section 1860D–
17 2(b)(2)(A) of the Social Security Act (42
18 U.S.C. 1395w–102(b)(2)(A)) is amended—

19 (i) in the subparagraph header, by
20 striking “25 PERCENT COINSURANCE” and
21 inserting “COINSURANCE”;

22 (ii) in clause (i), by inserting “(or, for
23 2024 and each subsequent year, 23 per-
24 cent)” after “25 percent”; and

1 (iii) in clause (ii), by inserting “(or,
2 for 2024 and each subsequent year, 23
3 percent)” after “25 percent”.

4 (B) CONFORMING AMENDMENT.—Section
5 1860D–14(a)(2)(D) of the Social Security Act
6 (42 U.S.C. 1395w–114(a)(2)(D)) is amended
7 by inserting “(or, for 2024 and each subsequent
8 year, instead of coinsurance of ‘23 percent’”
9 after “instead of coinsurance of ‘25 percent’”.

10 (2) BENEFICIARY PREMIUM PERCENTAGE.—

11 (A) IN GENERAL.—Section 1860D–
12 13(a)(3)(A) of the Social Security Act (42
13 U.S.C. 1395w–113(a)(3)(A)) is amended by in-
14 serting “(or, for 2024 and each subsequent
15 year, 23.5 percent)” after “25.5 percent”.

16 (B) CONFORMING AMENDMENTS.—

17 (i) Section 1860D–11(g)(6) of the So-
18 cial Security Act (42 U.S.C. 1395w–
19 111(g)(6)) is amended by inserting “(or,
20 for 2024 and each subsequent year, 23.5
21 percent)” after “25.5 percent”.

22 (ii) Section 1860D–13(a)(7)(B)(i) of
23 the Social Security Act (42 U.S.C. 1395w–
24 113(a)(7)(B)(i)) is amended—

1 (I) in subclause (I), by inserting
 2 “(or, for 2024 and each subsequent
 3 year, 23.5 percent)” after “25.5 per-
 4 cent”; and

5 (II) in subclause (II), by insert-
 6 ing “(or, for 2024 and each subse-
 7 quent year, 23.5 percent)” after “25.5
 8 percent”.

9 (iii) Section 1860D–15(a) of the So-
 10 cial Security Act (42 U.S.C. 1395w–
 11 115(a)) is amended by inserting “(or, for
 12 2024 and each subsequent year, 76.5 per-
 13 cent)” after “74.5 percent”.

14 (d) MANUFACTURER DISCOUNT PROGRAM.—

15 (1) IN GENERAL.—Part D of title XVIII of the
 16 Social Security Act (42 U.S.C. 1395w–101 through
 17 42 U.S.C. 1395w–153), as amended by section 202,
 18 is further amended by inserting after section
 19 1860D–14B the following new sections:

20 **“SEC. 1860D–14C. MANUFACTURER DISCOUNT PROGRAM.**

21 “(a) ESTABLISHMENT.—The Secretary shall estab-
 22 lish a manufacturer discount program (in this section re-
 23 ferred to as the ‘program’). Under the program, the Sec-
 24 retary shall enter into agreements described in subsection
 25 (b) with manufacturers and provide for the performance

1 of the duties described in subsection (c). The Secretary
2 shall establish a model agreement for use under the pro-
3 gram by not later than January 1, 2023, in consultation
4 with manufacturers, and allow for comment on such model
5 agreement.

6 “(b) TERMS OF AGREEMENT.—

7 “(1) IN GENERAL.—

8 “(A) AGREEMENT.—An agreement under
9 this section shall require the manufacturer to
10 provide, in accordance with this section, dis-
11 counted prices for applicable drugs of the man-
12 ufacturer that are dispensed to applicable bene-
13 ficiaries on or after January 1, 2024.

14 “(B) CLARIFICATION.—Nothing in this
15 section shall be construed as affecting—

16 “(i) the application of a coinsurance
17 of 23 percent of the negotiated price, as
18 applied under paragraph (2)(A) of section
19 1860D–2(b), for costs described in such
20 paragraph; or

21 “(ii) the application of the copayment
22 amount described in paragraph (4)(A) of
23 such section, with respect to costs de-
24 scribed in such paragraph.

25 “(C) TIMING OF AGREEMENT.—

1 “(i) SPECIAL RULE FOR 2024.—In
2 order for an agreement with a manufac-
3 turer to be in effect under this section with
4 respect to the period beginning on January
5 1, 2024, and ending on December 31,
6 2024, the manufacturer shall enter into
7 such agreement not later than 30 days
8 after the date of the establishment of a
9 model agreement under subsection (a).

10 “(ii) 2025 AND SUBSEQUENT
11 YEARS.—In order for an agreement with a
12 manufacturer to be in effect under this
13 section with respect to plan year 2025 or
14 a subsequent plan year, the manufacturer
15 shall enter into such agreement not later
16 than a calendar quarter or semi-annual
17 deadline established by the Secretary.

18 “(2) PROVISION OF APPROPRIATE DATA.—Each
19 manufacturer with an agreement in effect under this
20 section shall collect and have available appropriate
21 data, as determined by the Secretary, to ensure that
22 it can demonstrate to the Secretary compliance with
23 the requirements under the program.

24 “(3) COMPLIANCE WITH REQUIREMENTS FOR
25 ADMINISTRATION OF PROGRAM.—Each manufac-

1 turer with an agreement in effect under this section
2 shall comply with requirements imposed by the Sec-
3 retary or a third party with a contract under sub-
4 section (d)(3), as applicable, for purposes of admin-
5 istering the program, including any determination
6 under subparagraph (A) of subsection (c)(1) or pro-
7 cedures established under such subsection (c)(1).

8 “(4) LENGTH OF AGREEMENT.—

9 “(A) IN GENERAL.—An agreement under
10 this section shall be effective for an initial pe-
11 riod of not less than 12 months and shall be
12 automatically renewed for a period of not less
13 than 1 year unless terminated under subpara-
14 graph (B).

15 “(B) TERMINATION.—

16 “(i) BY THE SECRETARY.—The Sec-
17 retary shall provide for termination of an
18 agreement under this section for a knowing
19 and willful violation of the requirements of
20 the agreement or other good cause shown.
21 Such termination shall not be effective ear-
22 lier than 30 days after the date of notice
23 to the manufacturer of such termination.
24 The Secretary shall provide, upon request,
25 a manufacturer with a hearing concerning

1 such a termination, and such hearing shall
2 take place prior to the effective date of the
3 termination with sufficient time for such
4 effective date to be repealed if the Sec-
5 retary determines appropriate.

6 “(ii) BY A MANUFACTURER.—A man-
7 ufacturer may terminate an agreement
8 under this section for any reason. Any
9 such termination shall be effective, with re-
10 spect to a plan year—

11 “(I) if the termination occurs be-
12 fore January 31 of a plan year, as of
13 the day after the end of the plan year;
14 and

15 “(II) if the termination occurs on
16 or after January 31 of a plan year, as
17 of the day after the end of the suc-
18 ceeding plan year.

19 “(iii) EFFECTIVENESS OF TERMI-
20 NATION.—Any termination under this sub-
21 paragraph shall not affect discounts for
22 applicable drugs of the manufacturer that
23 are due under the agreement before the ef-
24 fective date of its termination.

1 “(iv) NOTICE TO THIRD PARTY.—The
2 Secretary shall provide notice of such ter-
3 mination to a third party with a contract
4 under subsection (d)(3) within not less
5 than 30 days before the effective date of
6 such termination.

7 “(c) DUTIES DESCRIBED.—The duties described in
8 this subsection are the following:

9 “(1) ADMINISTRATION OF PROGRAM.—Admin-
10 istering the program, including—

11 “(A) the determination of the amount of
12 the discounted price of an applicable drug of a
13 manufacturer;

14 “(B) the establishment of procedures to
15 ensure that, not later than the applicable num-
16 ber of calendar days after the dispensing of an
17 applicable drug by a pharmacy or mail order
18 service, the pharmacy or mail order service is
19 reimbursed for an amount equal to the dif-
20 ference between—

21 “(i) the negotiated price of the appli-
22 cable drug; and

23 “(ii) the discounted price of the appli-
24 cable drug;

1 “(C) the establishment of procedures to
2 ensure that the discounted price for an applica-
3 ble drug under this section is applied before any
4 coverage or financial assistance under other
5 health benefit plans or programs that provide
6 coverage or financial assistance for the pur-
7 chase or provision of prescription drug coverage
8 on behalf of applicable beneficiaries as specified
9 by the Secretary; and

10 “(D) providing a reasonable dispute resolu-
11 tion mechanism to resolve disagreements be-
12 tween manufacturers, applicable beneficiaries,
13 and the third party with a contract under sub-
14 section (d)(3).

15 “(2) MONITORING COMPLIANCE.—

16 “(A) IN GENERAL.—The Secretary shall
17 monitor compliance by a manufacturer with the
18 terms of an agreement under this section.

19 “(B) NOTIFICATION.—If a third party
20 with a contract under subsection (d)(3) deter-
21 mines that the manufacturer is not in compli-
22 ance with such agreement, the third party shall
23 notify the Secretary of such noncompliance for
24 appropriate enforcement under subsection (e).

1 “(3) COLLECTION OF DATA FROM PRESCRIP-
2 TION DRUG PLANS AND MA-PD PLANS.—The Sec-
3 retary may collect appropriate data from prescrip-
4 tion drug plans and MA-PD plans in a timeframe
5 that allows for discounted prices to be provided for
6 applicable drugs under this section.

7 “(d) ADMINISTRATION.—

8 “(1) IN GENERAL.—Subject to paragraph (2),
9 the Secretary shall provide for the implementation of
10 this section, including the performance of the duties
11 described in subsection (c).

12 “(2) LIMITATION.—In providing for the imple-
13 mentation of this section, the Secretary shall not re-
14 ceive or distribute any funds of a manufacturer
15 under the program.

16 “(3) CONTRACT WITH THIRD PARTIES.—The
17 Secretary shall enter into a contract with 1 or more
18 third parties to administer the requirements estab-
19 lished by the Secretary in order to carry out this
20 section. At a minimum, the contract with a third
21 party under the preceding sentence shall require
22 that the third party—

23 “(A) receive and transmit information be-
24 tween the Secretary, manufacturers, and other

1 individuals or entities the Secretary determines
2 appropriate;

3 “(B) receive, distribute, or facilitate the
4 distribution of funds of manufacturers to ap-
5 propriate individuals or entities in order to
6 meet the obligations of manufacturers under
7 agreements under this section;

8 “(C) provide adequate and timely informa-
9 tion to manufacturers, consistent with the
10 agreement with the manufacturer under this
11 section, as necessary for the manufacturer to
12 fulfill its obligations under this section; and

13 “(D) permit manufacturers to conduct
14 periodic audits, directly or through contracts, of
15 the data and information used by the third
16 party to determine discounts for applicable
17 drugs of the manufacturer under the program.

18 “(4) PERFORMANCE REQUIREMENTS.—The
19 Secretary shall establish performance requirements
20 for a third party with a contract under paragraph
21 (3) and safeguards to protect the independence and
22 integrity of the activities carried out by the third
23 party under the program under this section.

1 “(5) IMPLEMENTATION.—The Secretary shall
2 implement the program under this section for 2024
3 and 2025 by program instruction or otherwise.

4 “(e) ENFORCEMENT.—

5 “(1) AUDITS.—Each manufacturer with an
6 agreement in effect under this section shall be sub-
7 ject to periodic audit by the Secretary.

8 “(2) CIVIL MONEY PENALTY.—

9 “(A) IN GENERAL.—A manufacturer that
10 fails to provide discounted prices for applicable
11 drugs of the manufacturer dispensed to applica-
12 ble beneficiaries in accordance with such agree-
13 ment shall be subject to a civil money penalty
14 for each such failure in an amount the Sec-
15 retary determines is equal to the sum of—

16 “(i) the amount that the manufac-
17 turer would have paid with respect to such
18 discounts under the agreement, which will
19 then be used to pay the discounts which
20 the manufacturer had failed to provide;
21 and

22 “(ii) 25 percent of such amount.

23 “(B) APPLICATION.—The provisions of
24 section 1128A (other than subsections (a) and
25 (b)) shall apply to a civil money penalty under

1 this paragraph in the same manner as such
2 provisions apply to a penalty or proceeding
3 under section 1128A(a).

4 “(f) CLARIFICATION REGARDING AVAILABILITY OF
5 OTHER COVERED PART D DRUGS.—Nothing in this sec-
6 tion shall prevent an applicable beneficiary from pur-
7 chasing a covered part D drug that is not an applicable
8 drug (including a generic drug or a drug that is not on
9 the formulary of the prescription drug plan or MA–PD
10 plan that the applicable beneficiary is enrolled in).

11 “(g) DEFINITIONS.—In this section:

12 “(1) APPLICABLE BENEFICIARY.—The term
13 ‘applicable beneficiary’ means an individual who, on
14 the date of dispensing a covered part D drug—

15 “(A) is enrolled in a prescription drug plan
16 or an MA–PD plan;

17 “(B) is not enrolled in a qualified retiree
18 prescription drug plan; and

19 “(C) has incurred costs, as determined in
20 accordance with section 1860D–2(b)(4)(C) as if
21 clause (iii) of such section included a reference
22 to costs reimbursed through insurance, a group
23 health plan, or certain other third-party pay-
24 ment arrangements, for covered part D drugs
25 in the year that exceed—

1 “(i) in the case of an individual not
 2 described in clause (ii) or (iii), the annual
 3 deductible for such year, as specified in
 4 section 1860D–2(b)(1);

5 “(ii) in the case of a subsidy eligible
 6 individual described in section 1860D–
 7 14(a)(1), the annual deductible for such
 8 year, as specified in subparagraph (B) of
 9 such section; and

10 “(iii) in the case of a subsidy eligible
 11 individual described in section 1860D–
 12 14(a)(2), the annual deductible for such
 13 year, as specified in subparagraph (B) of
 14 such section.

15 “(2) APPLICABLE DRUG.—The term ‘applicable
 16 drug’, with respect to an applicable beneficiary—

17 “(A) means a covered part D drug—

18 “(i) approved under a new drug appli-
 19 cation under section 505(c) of the Federal
 20 Food, Drug, and Cosmetic Act or, in the
 21 case of a biologic product, licensed under
 22 section 351 of the Public Health Service
 23 Act; and

24 “(ii)(I) if the PDP sponsor of the pre-
 25 scription drug plan or the MA organization

1 offering the MA–PD plan uses a for-
 2 mulary, which is on the formulary of the
 3 prescription drug plan or MA–PD plan
 4 that the applicable beneficiary is enrolled
 5 in;

6 “(II) if the PDP sponsor of the pre-
 7 scription drug plan or the MA organization
 8 offering the MA–PD plan does not use a
 9 formulary, for which benefits are available
 10 under the prescription drug plan or MA–
 11 PD plan that the applicable beneficiary is
 12 enrolled in; or

13 “(III) is provided through an excep-
 14 tion or appeal; and

15 “(B) does not include a selected drug (as
 16 referred to under section 1192(c)) during a
 17 price applicability period (as defined in section
 18 1191(b)(2)) with respect to such drug.

19 “(3) APPLICABLE NUMBER OF CALENDAR
 20 DAYS.—The term ‘applicable number of calendar
 21 days’ means—

22 “(A) with respect to claims for reimburse-
 23 ment submitted electronically, 14 days; and

24 “(B) with respect to claims for reimburse-
 25 ment submitted otherwise, 30 days.

1 “(4) DISCOUNTED PRICE.—

2 “(A) IN GENERAL.—The term ‘discounted
3 price’ means, subject to subparagraphs (B) and
4 (C), with respect to an applicable drug of a
5 manufacturer dispensed during a year to an ap-
6 plicable beneficiary—

7 “(i) who has not incurred costs, as de-
8 termined in accordance with section
9 1860D–2(b)(4)(C), for covered part D
10 drugs in the year that are equal to or ex-
11 ceed the annual out-of-pocket threshold
12 specified in section 1860D–2(b)(4)(B)(i)
13 for the year, 90 percent of the negotiated
14 price of such drug; and

15 “(ii) who has incurred such costs, as
16 so determined, in the year that are equal
17 to or exceed such threshold for the year,
18 80 percent of the negotiated price of such
19 drug.

20 “(B) PHASE-IN FOR CERTAIN DRUGS DIS-
21 PENSED TO LIS BENEFICIARIES.—

22 “(i) IN GENERAL.—In the case of an
23 applicable drug of a specified manufacturer
24 (as defined in clause (ii)) that is marketed
25 as of the date of enactment of this sub-

1 paragraph and dispensed for an applicable
2 beneficiary who is a subsidy eligible indi-
3 vidual (as defined in section 1860D–
4 14(a)(3)), the term ‘discounted price’
5 means the specified LIS percent (as de-
6 fined in clause (iii)) of the negotiated price
7 of the applicable drug of the manufacturer.

8 “(ii) SPECIFIED MANUFACTURER.—

9 “(I) IN GENERAL.—In this sub-
10 paragraph, subject to subclause (II),
11 the term ‘specified manufacturer’
12 means a manufacturer of an applica-
13 ble drug for which, in 2021—

14 “(aa) the manufacturer had
15 a coverage gap discount agree-
16 ment under section 1860D–14A;

17 “(bb) the total expenditures
18 for all of the specified drugs of
19 the manufacturer covered by
20 such agreement or agreements
21 for such year and covered under
22 this part during such year rep-
23 resented less than 1.0 percent of
24 the total expenditures under this

1 part for all covered Part D drugs
2 during such year; and

3 “(cc) the total expenditures
4 for all of the specified drugs of
5 the manufacturer that are single
6 source drugs and biological prod-
7 ucts covered under part B during
8 such year represented less than
9 1.0 percent of the total expendi-
10 tures under part B for all drugs
11 or biological products covered
12 under such part during such
13 year.

14 “(II) SPECIFIED DRUGS.—

15 “(aa) IN GENERAL.—For
16 purposes of this clause, the term
17 ‘specified drug’ means, with re-
18 spect to a specified manufac-
19 turer, for 2021, an applicable
20 drug that is produced, prepared,
21 propagated, compounded, con-
22 verted, or processed by the man-
23 ufacturer.

24 “(bb) AGGREGATION
25 RULE.—All persons treated as a

1 single employer under subsection
2 (a) or (b) of section 52 of the In-
3 ternal Revenue Code of 1986
4 shall be treated as one manufac-
5 turer for purposes of this sub-
6 paragraph. For purposes of mak-
7 ing a determination pursuant to
8 the previous sentence, an agree-
9 ment under this section shall re-
10 quire that a manufacturer pro-
11 vide and attest to such informa-
12 tion as specified by the Secretary
13 as necessary.

14 “(III) LIMITATION.—The term
15 ‘specified manufacturer’ shall not in-
16 clude a manufacturer described in
17 subclause (I) if such manufacturer is
18 acquired after 2021 by another manu-
19 facturer that is not a specified manu-
20 facturer, effective at the beginning of
21 the plan year immediately following
22 such acquisition or, in the case of an
23 acquisition before 2024, effective Jan-
24 uary 1, 2024.

1 “(iii) SPECIFIED LIS PERCENT.—In
2 this subparagraph, the ‘specified LIS per-
3 cent’ means, with respect to a year—

4 “(I) for an applicable drug dis-
5 pensed for an applicable beneficiary
6 described in clause (i) who has not in-
7 curred costs, as determined in accord-
8 ance with section 1860D–2(b)(4)(C),
9 for covered part D drugs in the year
10 that are equal to or exceed the annual
11 out-of-pocket threshold specified in
12 section 1860D–2(b)(4)(B)(i) for the
13 year—

14 “(aa) for 2024, 99 percent;

15 “(bb) for 2025, 98 percent;

16 “(cc) for 2026, 95 percent;

17 “(dd) for 2027, 92 percent;

18 and

19 “(ee) for 2028 and each
20 subsequent year, 90 percent; and

21 “(II) for an applicable drug dis-
22 pensed for an applicable beneficiary
23 described in clause (i) who has in-
24 curred costs, as determined in accord-
25 ance with section 1860D–2(b)(4)(C),

for covered part D drugs in the year
that are equal to or exceed the annual
out-of-pocket threshold specified in
section 1860D–2(b)(4)(B)(i) for the
year—

“(aa) for 2024, 99 percent;

“(bb) for 2025, 98 percent;

“(cc) for 2026, 95 percent;

“(dd) for 2027, 92 percent;

“(ee) for 2028, 90 percent;

“(ff) for 2029, 85 percent;

and

“(gg) for 2030 and each

subsequent year, 80 percent.

“(C) PHASE-IN FOR SPECIFIED SMALL
MANUFACTURERS.—

“(i) IN GENERAL.—In the case of an
applicable drug of a specified small manu-
facturer (as defined in clause (ii)) that is
marketed as of the date of enactment of
this subparagraph and dispensed for an
applicable beneficiary, the term ‘discounted
price’ means the specified small manufac-
turer percent (as defined in clause (iii)) of

1 the negotiated price of the applicable drug
2 of the manufacturer.

3 “(ii) SPECIFIED SMALL MANUFAC-
4 TURER.—

5 “(I) IN GENERAL.—In this sub-
6 paragraph, subject to subclause (III),
7 the term ‘specified small manufac-
8 turer’ means a manufacturer of an
9 applicable drug for which, in 2021—

10 “(aa) the manufacturer is a
11 specified manufacturer (as de-
12 fined in subparagraph (B)(ii));
13 and

14 “(bb) the total expenditures
15 under part D for any one of the
16 specified small manufacturer
17 drugs of the manufacturer that
18 are covered by the agreement or
19 agreements under section
20 1860D–14A of such manufac-
21 turer for such year and covered
22 under this part during such year
23 are equal to or more than 80 per-
24 cent of the total expenditures
25 under this part for all specified

1 small manufacturer drugs of the
2 manufacturer that are covered by
3 such agreement or agreements
4 for such year and covered under
5 this part during such year.

6 “(II) SPECIFIED SMALL MANU-
7 FACTURER DRUGS.—

8 “(aa) IN GENERAL.—For
9 purposes of this clause, the term
10 ‘specified small manufacturer
11 drugs’ means, with respect to a
12 specified small manufacturer, for
13 2021, an applicable drug that is
14 produced, prepared, propagated,
15 compounded, converted, or proc-
16 essed by the manufacturer.

17 “(bb) AGGREGATION
18 RULE.—All persons treated as a
19 single employer under subsection
20 (a) or (b) of section 52 of the In-
21 ternal Revenue Code of 1986
22 shall be treated as one manufac-
23 turer for purposes of this sub-
24 paragraph. For purposes of mak-
25 ing a determination pursuant to

1 the previous sentence, an agree-
2 ment under this section shall re-
3 quire that a manufacturer pro-
4 vide and attest to such informa-
5 tion as specified by the Secretary
6 as necessary.

7 “(III) LIMITATION.—The term
8 ‘specified small manufacturer’ shall
9 not include a manufacturer described
10 in subclause (I) if such manufacturer
11 is acquired after 2021 by another
12 manufacturer that is not a specified
13 small manufacturer, effective at the
14 beginning of the plan year imme-
15 diately following such acquisition or,
16 in the case of an acquisition before
17 2024, effective January 1, 2024.

18 “(iii) SPECIFIED SMALL MANUFAC-
19 Turer PERCENT.—In this subparagraph,
20 the term ‘specified small manufacturer per-
21 cent’ means, with respect to a year—

22 “(I) for an applicable drug dis-
23 pensed for an applicable beneficiary
24 who has not incurred costs, as deter-
25 mined in accordance with section

1 1860D–2(b)(4)(C), for covered part D
2 drugs in the year that are equal to or
3 exceed the annual out-of-pocket
4 threshold specified in section 1860D–
5 2(b)(4)(B)(i) for the year—

6 “(aa) for 2024, 99 percent;

7 “(bb) for 2025, 98 percent;

8 “(cc) for 2026, 95 percent;

9 “(dd) for 2027, 92 percent;

10 and

11 “(ee) for 2028 and each
12 subsequent year, 90 percent; and

13 “(II) for an applicable drug dis-
14 pensed for an applicable beneficiary
15 who has incurred costs, as determined
16 in accordance with section 1860D–
17 2(b)(4)(C), for covered part D drugs
18 in the year that are equal to or exceed
19 the annual out-of-pocket threshold
20 specified in section 1860D–
21 2(b)(4)(B)(i) for the year—

22 “(aa) for 2024, 99 percent;

23 “(bb) for 2025, 98 percent;

24 “(cc) for 2026, 95 percent;

25 “(dd) for 2027, 92 percent;

1 “(ee) for 2028, 90 percent;
2 “(ff) for 2029, 85 percent;
3 and
4 “(gg) for 2030 and each
5 subsequent year, 80 percent.

6 “(D) TOTAL EXPENDITURES.—For pur-
7 poses of this paragraph, the term ‘total expend-
8 itures’ includes, in the case of expenditures with
9 respect to part D, ingredient costs, dispensing
10 fees, sales tax, and, if applicable, vaccine ad-
11 ministration fees. The term ‘total expenditures’
12 excludes, in the case of expenditures with re-
13 spect to part B, expenditures for a drug or bio-
14 logical that are bundled or packaged into the
15 payment for another service.

16 “(E) SPECIAL CASE FOR CERTAIN
17 CLAIMS.—

18 “(i) CLAIMS SPANNING DEDUCT-
19 IBLE.—In the case where the entire
20 amount of the negotiated price of an indi-
21 vidual claim for an applicable drug with re-
22 spect to an applicable beneficiary does not
23 fall above the annual deductible specified
24 in section 1860D–2(b)(1) for the year, the
25 manufacturer of the applicable drug shall

1 provide the discounted price under this
2 section on only the portion of the nego-
3 tiated price of the applicable drug that
4 falls above such annual deductible.

5 “(ii) CLAIMS SPANNING OUT-OF-POCK-
6 ET THRESHOLD.—In the case where the
7 entire amount of the negotiated price of an
8 individual claim for an applicable drug
9 with respect to an applicable beneficiary
10 does not fall entirely below or entirely
11 above the annual out-of-pocket threshold
12 specified in section 1860D–2(b)(4)(B)(i)
13 for the year, the manufacturer of the ap-
14 plicable drug shall provide the discounted
15 price—

16 “(I) in accordance with subpara-
17 graph (A)(i) on the portion of the ne-
18 gotiated price of the applicable drug
19 that falls below such threshold; and

20 “(II) in accordance with subpara-
21 graph (A)(ii) on the portion of such
22 price of such drug that falls at or
23 above such threshold.

24 “(5) MANUFACTURER.—The term ‘manufac-
25 turer’ means any entity which is engaged in the pro-

1 duction, preparation, propagation, compounding,
2 conversion, or processing of prescription drug prod-
3 ucts, either directly or indirectly by extraction from
4 substances of natural origin, or independently by
5 means of chemical synthesis, or by a combination of
6 extraction and chemical synthesis. Such term does
7 not include a wholesale distributor of drugs or a re-
8 tail pharmacy licensed under State law.

9 “(6) NEGOTIATED PRICE.—The term ‘nego-
10 tiated price’ has the meaning given such term in sec-
11 tion 423.100 of title 42, Code of Federal Regula-
12 tions (or any successor regulation) and, with respect
13 to an applicable drug, such negotiated price shall in-
14 clude any dispensing fee and, if applicable, any vac-
15 cine administration fee for the applicable drug.

16 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
17 PLAN.—The term ‘qualified retiree prescription drug
18 plan’ has the meaning given such term in section
19 1860D–22(a)(2).

20 **“SEC. 1860D–14D. SELECTED DRUG SUBSIDY PROGRAM.**

21 “With respect to covered part D drugs that would
22 be applicable drugs (as defined in section 1860D–
23 14C(g)(2)) but for the application of subparagraph (B)
24 of such section, the Secretary shall provide a process
25 whereby, in the case of an applicable beneficiary (as de-

1 fined in section 1860D–14C(g)(1)) who, with respect to
 2 a year, is enrolled in a prescription drug plan or is enrolled
 3 in an MA–PD plan, has not incurred costs that are equal
 4 to or exceed the annual out-of-pocket threshold specified
 5 in section 1860D–2(b)(4)(B)(i), and is dispensed such a
 6 drug the Secretary (periodically and on a timely basis)
 7 provides the PDP sponsor or the MA organization offering
 8 the plan, a subsidy with respect to such drug that is equal
 9 to 10 percent of the negotiated price (as defined in section
 10 1860D–14C(g)(6)) of such drug.”.

11 (2) SUNSET OF MEDICARE COVERAGE GAP DIS-
 12 COUNT PROGRAM.—Section 1860D–14A of the So-
 13 cial Security Act (42 U.S.C. 1395–114a) is amend-
 14 ed—

15 (A) in subsection (a), in the first sentence,
 16 by striking “The Secretary” and inserting
 17 “Subject to subsection (h), the Secretary”; and

18 (B) by adding at the end the following new
 19 subsection:

20 “(h) SUNSET OF PROGRAM.—

21 “(1) IN GENERAL.—The program shall not
 22 apply with respect to applicable drugs dispensed on
 23 or after January 1, 2024, and, subject to paragraph
 24 (2), agreements under this section shall be termi-
 25 nated as of such date.

1 “(2) CONTINUED APPLICATION FOR APPLICA-
 2 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
 3 provisions of this section (including all responsibil-
 4 ities and duties) shall continue to apply on and after
 5 January 1, 2024, with respect to applicable drugs
 6 dispensed prior to such date.”.

7 (3) INCLUSION OF ACTUARIAL VALUE OF MANU-
 8 FACTURER DISCOUNTS IN BIDS.—Section 1860D–11
 9 of the Social Security Act (42 U.S.C. 1395w–111)
 10 is amended—

11 (A) in subsection (b)(2)(C)(iii)—

12 (i) by striking “assumptions regarding
 13 the reinsurance” and inserting “assump-
 14 tions regarding—

15 “(I) the reinsurance”; and

16 (ii) by adding at the end the fol-
 17 lowing:

18 “(II) for 2024 and each subse-
 19 quent year, the manufacturer dis-
 20 counts provided under section 1860D–
 21 14C subtracted from the actuarial
 22 value to produce such bid; and”; and

23 (B) in subsection (c)(1)(C)—

(i) by striking “an actuarial valuation of the reinsurance” and inserting “an actuarial valuation of—

“(i) the reinsurance”;

(ii) in clause (i), as inserted by clause (i) of this subparagraph, by adding “and” at the end; and

(iii) by adding at the end the following:

“(ii) for 2024 and each subsequent year, the manufacturer discounts provided under section 1860D–14C;”.

(e) CONFORMING AMENDMENTS.—

(1) Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(A) in subsection (a)(2)(A)(i)(I), by striking “, or an increase in the initial” and inserting “or, for a year preceding 2024, an increase in the initial”;

(B) in subsection (c)(1)(C)—

(i) in the subparagraph heading, by striking “AT INITIAL COVERAGE LIMIT”; and

(ii) by inserting “for a year preceding 2024 or the annual out-of-pocket threshold

1 specified in subsection (b)(4)(B) for the
 2 year for 2024 and each subsequent year”
 3 after “subsection (b)(3) for the year” each
 4 place it appears; and

5 (C) in subsection (d)(1)(A), by striking “or
 6 an initial” and inserting “or, for a year pre-
 7 ceding 2024, an initial”.

8 (2) Section 1860D–4(a)(4)(B)(i) of the Social
 9 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
 10 amended by striking “the initial” and inserting “for
 11 a year preceding 2024, the initial”.

12 (3) Section 1860D–14(a) of the Social Security
 13 Act (42 U.S.C. 1395w–114(a)) is amended—

14 (A) in paragraph (1)—

15 (i) in subparagraph (C), by striking
 16 “The continuation” and inserting “For a
 17 year preceding 2024, the continuation”;

18 (ii) in subparagraph (D)(iii), by strik-
 19 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
 20 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and

21 (iii) in subparagraph (E), by striking
 22 “The elimination” and inserting “For a
 23 year preceding 2024, the elimination”; and

24 (B) in paragraph (2)—

1 (i) in subparagraph (C), by striking
2 “The continuation” and inserting “For a
3 year preceding 2024, the continuation”;
4 and

5 (ii) in subparagraph (E), by striking
6 “1860D–2(b)(4)(A)(i)(I)” and inserting
7 “1860D–2(b)(4)(A)(i)(I)(aa)”.

8 (4) Section 1860D–21(d)(7) of the Social Secu-
9 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended
10 by striking “section 1860D–2(b)(4)(B)(i)” and in-
11 serting “section 1860D–2(b)(4)(C)(i)”.

12 (5) Section 1860D–22(a)(2)(A) of the Social
13 Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is
14 amended—

15 (A) by striking “the value of any discount”
16 and inserting the following: “the value of—

17 “(i) for years prior to 2024, any dis-
18 count”;

19 (B) in clause (i), as inserted by subpara-
20 graph (A) of this paragraph, by striking the pe-
21 riod at the end and inserting “; and”; and

22 (C) by adding at the end the following new
23 clause:

1 “(ii) for 2024 and each subsequent
2 year, any discount provided pursuant to
3 section 1860D–14C.”.

4 (6) Section 1860D–41(a)(6) of the Social Secu-
5 rity Act (42 U.S.C. 1395w–151(a)(6)) is amended—

6 (A) by inserting “for a year before 2024”
7 after “1860D–2(b)(3)”; and

8 (B) by inserting “for such year” before the
9 period.

10 (7) Section 1860D–43 of the Social Security
11 Act (42 U.S.C. 1395w–153) is amended—

12 (A) in subsection (a)—

13 (i) by striking paragraph (1) and in-
14 serting the following:

15 “(1) participate in—

16 “(A) for 2011 through 2023, the Medicare
17 coverage gap discount program under section
18 1860D–14A; and

19 “(B) for 2024 and each subsequent year,
20 the manufacturer discount program under sec-
21 tion 1860D–14C;”;

22 (ii) by striking paragraph (2) and in-
23 serting the following:

24 “(2) have entered into and have in effect—

1 “(A) for 2011 through 2023, an agreement
 2 described in subsection (b) of section 1860D–
 3 14A with the Secretary; and

4 “(B) for 2024 and each subsequent year,
 5 an agreement described in subsection (b) of sec-
 6 tion 1860D–14C with the Secretary; and”; and

7 (iii) by striking paragraph (3) and in-
 8 serting the following:

9 “(3) have entered into and have in effect, under
 10 terms and conditions specified by the Secretary—

11 “(A) for 2011 through 2023, a contract
 12 with a third party that the Secretary has en-
 13 tered into a contract with under subsection
 14 (d)(3) of section 1860D–14A; and

15 “(B) for 2024 and each subsequent year,
 16 a contract with a third party that the Secretary
 17 has entered into a contract with under sub-
 18 section (d)(3) of section 1860D–14C.”; and

19 (B) by striking subsection (b) and insert-
 20 ing the following:

21 “(b) EFFECTIVE DATE.—Paragraphs (1)(A), (2)(A),
 22 and (3)(A) of subsection (a) shall apply to covered part
 23 D drugs dispensed under this part on or after January
 24 1, 2011, and before January 1, 2024, and paragraphs
 25 (1)(B), (2)(B), and (3)(B) of such subsection shall apply

1 to covered part D drugs dispensed under this part on or
2 after January 1, 2024.”.

3 (8) Section 1927 of the Social Security Act (42
4 U.S.C. 1396r–8) is amended—

5 (A) in subsection (c)(1)(C)(i)(VI), by in-
6 serting before the period at the end the fol-
7 lowing: “or under the manufacturer discount
8 program under section 1860D–14C”; and

9 (B) in subsection (k)(1)(B)(i)(V), by in-
10 serting before the period at the end the fol-
11 lowing: “or under section 1860D–14C”.

12 (f) IMPLEMENTATION FOR 2024 AND 2025.—Not-
13 withstanding any other provision of this section, the Sec-
14 retary shall implement this section, including the amend-
15 ments made by this section, for 2024 and 2025 by pro-
16 gram instruction or otherwise.

17 (g) FUNDING.—In addition to amounts otherwise
18 available, there are appropriated to the Centers for Medi-
19 care & Medicaid Services, out of any money in the Treas-
20 ury not otherwise appropriated, \$44,000,000 for fiscal
21 year 2022, \$38,000,000 for fiscal year 2023, and
22 \$32,000,000 for each of fiscal years 2024 through 2031,
23 to remain available until expended, to carry out the provi-
24 sions of, including the amendments made by, this section.

1 **SEC. 302. MAXIMUM MONTHLY CAP ON COST-SHARING PAY-**
2 **MENTS UNDER PRESCRIPTION DRUG PLANS**
3 **AND MA-PD PLANS.**

4 (a) IN GENERAL.—Section 1860D–2(b) of the Social
5 Security Act (42 U.S.C. 1395w–102(b)), as amended by
6 section 301, is amended—

7 (1) in paragraph (2)—

8 (A) in subparagraph (A), by striking “and
9 (D)” and inserting “, (D), and (E)”; and

10 (B) by adding at the end the following new
11 subparagraph:

12 “(E) MAXIMUM MONTHLY CAP ON COST-
13 SHARING PAYMENTS.—

14 “(i) IN GENERAL.—For plan years be-
15 ginning on or after January 1, 2025, each
16 PDP sponsor offering a prescription drug
17 plan and each MA organization offering an
18 MA–PD plan shall provide to any enrollee
19 of such plan, including an enrollee who is
20 a subsidy eligible individual (as defined in
21 paragraph (3) of section 1860D–14(a)),
22 the option to elect with respect to a plan
23 year to pay cost-sharing under the plan in
24 monthly amounts that are capped in ac-
25 cordance with this subparagraph.

1 “(ii) DETERMINATION OF MAXIMUM
2 MONTHLY CAP.—For each month in the
3 plan year for which an enrollee in a pre-
4 scription drug plan or an MA–PD plan has
5 made an election pursuant to clause (i),
6 the PDP sponsor or MA organization shall
7 determine a maximum monthly cap (as de-
8 fined in clause (iv)) for such enrollee.

9 “(iii) BENEFICIARY MONTHLY PAY-
10 MENTS.—With respect to an enrollee who
11 has made an election pursuant to clause
12 (i), for each month described in clause (ii),
13 the PDP sponsor or MA organization shall
14 bill such enrollee an amount (not to exceed
15 the maximum monthly cap) for the out-of-
16 pocket costs of such enrollee in such
17 month.

18 “(iv) MAXIMUM MONTHLY CAP DE-
19 FINED.—In this subparagraph, the term
20 ‘maximum monthly cap’ means, with re-
21 spect to an enrollee—

22 “(I) for the first month for which
23 the enrollee has made an election pur-
24 suant to clause (i), an amount deter-
25 mined by calculating—

1 “(aa) the annual out-of-
2 pocket threshold specified in
3 paragraph (4)(B) minus the in-
4 curred costs of the enrollee as de-
5 scribed in paragraph (4)(C); di-
6 vided by

7 “(bb) the number of months
8 remaining in the plan year; and

9 “(II) for a subsequent month, an
10 amount determined by calculating—

11 “(aa) the sum of any re-
12 maining out-of-pocket costs owed
13 by the enrollee from a previous
14 month that have not yet been
15 billed to the enrollee and any ad-
16 ditional out-of-pocket costs in-
17 curred by the enrollee; divided by

18 “(bb) the number of months
19 remaining in the plan year.

20 “(v) ADDITIONAL REQUIREMENTS.—

21 The following requirements shall apply
22 with respect to the option to make an elec-
23 tion pursuant to clause (i) under this sub-
24 paragraph:

1 “(I) SECRETARIAL RESPONSIBIL-
2 ITIES.—The Secretary shall provide
3 information to part D eligible individ-
4 uals on the option to make such elec-
5 tion through educational materials, in-
6 cluding through the notices provided
7 under section 1804(a).

8 “(II) TIMING OF ELECTION.—An
9 enrollee in a prescription drug plan or
10 an MA–PD plan may make such an
11 election—

12 “(aa) prior to the beginning
13 of the plan year; or

14 “(bb) in any month during
15 the plan year.

16 “(III) PDP SPONSOR AND MA
17 ORGANIZATION RESPONSIBILITIES.—
18 Each PDP sponsor offering a pre-
19 scription drug plan or MA organiza-
20 tion offering an MA–PD plan—

21 “(aa) may not limit the op-
22 tion for an enrollee to make such
23 an election to certain covered
24 part D drugs;

1 “(bb) shall, prior to the plan
2 year, notify prospective enrollees
3 of the option to make such an
4 election in promotional materials;

5 “(cc) shall include informa-
6 tion on such option in enrollee
7 educational materials;

8 “(dd) shall have in place a
9 mechanism to notify a pharmacy
10 during the plan year when an en-
11 rollee incurs out-of-pocket costs
12 with respect to covered part D
13 drugs that make it likely the en-
14 rollee may benefit from making
15 such an election;

16 “(ee) shall provide that a
17 pharmacy, after receiving a noti-
18 fication described in item (dd)
19 with respect to an enrollee, in-
20 forms the enrollee of such notifi-
21 cation;

22 “(ff) shall ensure that such
23 an election by an enrollee has no
24 effect on the amount paid to
25 pharmacies (or the timing of

1 such payments) with respect to
2 covered part D drugs dispensed
3 to the enrollee; and

4 “(gg) shall have in place a
5 financial reconciliation process to
6 correct inaccuracies in payments
7 made by an enrollee under this
8 subparagraph with respect to
9 covered part D drugs during the
10 plan year.

11 “(IV) FAILURE TO PAY AMOUNT
12 BILLED.—If an enrollee fails to pay
13 the amount billed for a month as re-
14 quired under this subparagraph, the
15 election of the enrollee pursuant to
16 clause (i) shall be terminated and the
17 enrollee shall pay the cost-sharing
18 otherwise applicable for any covered
19 part D drugs subsequently dispensed
20 to the enrollee up to the annual out-
21 of-pocket threshold specified in para-
22 graph (4)(B).

23 “(V) CLARIFICATION REGARDING
24 PAST DUE AMOUNTS.—Nothing in this
25 subparagraph shall be construed as

1 prohibiting a PDP sponsor or an MA
 2 organization from billing an enrollee
 3 for an amount owed under this sub-
 4 paragraph.

5 “(VI) TREATMENT OF UNSET-
 6 TLED BALANCES.—Any unsettled bal-
 7 ances with respect to amounts owed
 8 under this subparagraph shall be
 9 treated as plan losses and the Sec-
 10 retary shall not be liable for any such
 11 balances outside of those assumed as
 12 losses estimated in plan bids.”; and

13 (2) in paragraph (4)—

14 (A) in subparagraph (C), by striking “in
 15 subparagraph (E)” and inserting “in subpara-
 16 graph (E) and subject to subparagraph (F)”;
 17 and

18 (B) by adding at the end the following new
 19 subparagraph:

20 “(F) INCLUSION OF COSTS PAID UNDER
 21 MAXIMUM MONTHLY CAP OPTION.—In applying
 22 subparagraph (A), with respect to an enrollee
 23 who has made an election pursuant to clause (i)
 24 of paragraph (2)(E), costs shall be treated as
 25 incurred if such costs are paid by a PDP spon-

1 sor or an MA organization under the option
2 provided under such paragraph.”.

3 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION
4 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-
5 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-
6 ing at the end the following new paragraph:

7 “(4) SAME MAXIMUM MONTHLY CAP ON COST-
8 SHARING.—For plan years beginning on or after
9 January 1, 2025, the maximum monthly cap on
10 cost-sharing payments under the option provided
11 under subsection (b)(2)(E) shall apply to such cov-
12 erage.”.

13 (c) IMPLEMENTATION FOR 2025.—The Secretary
14 shall implement this section, including the amendments
15 made by this section, for 2025 by program instruction or
16 otherwise.

17 (d) FUNDING.—In addition to amounts otherwise
18 available, there are appropriated to the Centers for Medi-
19 care & Medicaid Services, out of any money in the Treas-
20 ury not otherwise appropriated, \$1,000,000 for each of fis-
21 cal years 2022 through 2031, to remain available until ex-
22 pended, to carry out the provisions of, including the
23 amendments made by, this section.

1 **TITLE IV—REPEAL OF CERTAIN**
2 **PRESCRIPTION DRUG RE-**
3 **BATE RULE**

4 **SEC. 401. PROHIBITING IMPLEMENTATION OF RULE RELAT-**
5 **ING TO ELIMINATING THE ANTI-KICKBACK**
6 **STATUTE SAFE HARBOR PROTECTION FOR**
7 **PRESCRIPTION DRUG REBATES.**

8 Beginning January 1, 2026, the Secretary of Health
9 and Human Services shall not implement, administer, or
10 enforce the provisions of the final rule published by the
11 Office of the Inspector General of the Department of
12 Health and Human Services on November 30, 2020, and
13 titled “Fraud and Abuse; Removal of Safe Harbor Protec-
14 tion for Rebates Involving Prescription Pharmaceuticals
15 and Creation of New Safe Harbor Protection for Certain
16 Point-of-Sale Reductions in Price on Prescription Phar-
17 maceuticals and Certain Pharmacy Benefit Manager Serv-
18 ice Fees” (85 Fed. Reg. 76666).

19 **TITLE V—MISCELLANEOUS**

20 **SEC. 501. APPROPRIATE COST-SHARING FOR CERTAIN IN-**
21 **SULIN PRODUCTS UNDER MEDICARE PART D.**

22 (a) IN GENERAL.—Section 1860D–2 of the Social
23 Security Act (42 U.S.C. 1395w–102) is amended—

24 (1) in subsection (b)—

1 (A) in paragraph (1)(A), by striking “The
2 coverage” and inserting “Subject to paragraph
3 (8), the coverage”;

4 (B) in paragraph (2)(A), by striking “and
5 (D)” and inserting “and (D) and paragraph
6 (8)”;

7 (C) in paragraph (3)(A), by striking “and
8 (4)” and inserting “(4), and (8)”;

9 (D) in paragraph (4)(A)(i), by striking
10 “The coverage” and inserting “Subject to para-
11 graph (8), the coverage”; and

12 (E) by adding at the end the following new
13 paragraph:

14 “(8) TREATMENT OF COST-SHARING FOR CER-
15 TAIN INSULIN PRODUCTS.—

16 “(A) IN GENERAL.—For plan years begin-
17 ning on or after January 1, 2023, the following
18 shall apply with respect to insulin products (as
19 defined in subparagraph (B)):

20 “(i) NO APPLICATION OF DEDUCT-
21 IBLE.—The deductible under paragraph
22 (1) shall not apply with respect to such in-
23 sulin products.

24 “(ii) APPLICATION OF COST-SHAR-
25 ING.—

1 “(I) PLAN YEAR 2023.—For plan
2 year 2023, the coverage provides ben-
3 efits for such insulin products, regard-
4 less of whether an individual has
5 reached the initial coverage limit
6 under paragraph (3) or the out-of-
7 pocket threshold under paragraph (4),
8 with cost-sharing that is equal to the
9 applicable copayment amount.

10 “(II) PLAN YEAR 2024 AND SUB-
11 SEQUENT PLAN YEARS.—For plan
12 year 2024 and subsequent plan years,
13 the coverage provides benefits for
14 such insulin products, prior to an in-
15 dividual reaching the out-of-pocket
16 threshold under paragraph (4), with
17 cost-sharing that is equal to the appli-
18 cable copayment amount.

19 “(III) APPLICABLE COPAYMENT
20 AMOUNT.—For purposes of this
21 clause, the term ‘applicable copayment
22 amount’ means, with respect to an in-
23 sulin product under a prescription
24 drug plan or an MA–PD plan, an
25 amount that is not more than \$35.

1 “(B) INSULIN PRODUCT.—For purposes of
2 this paragraph, the term ‘insulin product’
3 means an insulin product that is approved
4 under section 505 of the Federal Food, Drug,
5 and Cosmetic Act or licensed under section 351
6 of the Public Health Service Act and marketed
7 pursuant to such approval or licensure, includ-
8 ing any insulin product that has been deemed
9 to be licensed under section 351 of the Public
10 Health Service Act pursuant to section
11 7002(e)(4) of the Biologics Price Competition
12 and Innovation Act of 2009 and marketed pur-
13 suant to such section.”; and

14 (2) in subsection (c), by adding at the end the
15 following new paragraph:

16 “(4) TREATMENT OF COST-SHARING FOR INSU-
17 LIN PRODUCTS.—The coverage is provided in accord-
18 ance with subsection (b)(8).”.

19 (b) CONFORMING AMENDMENTS TO COST-SHARING
20 FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)
21 of the Social Security Act (42 U.S.C. 1395w–114(a)) is
22 amended—

23 (1) in paragraph (1)—

24 (A) in subparagraph (D)(iii), by adding at
25 the end the following new sentence: “For plan

1 year 2023 and subsequent plan years, the co-
2 payment amount applicable under the preceding
3 sentence to an insulin product (as defined in
4 section 1860D–2(b)(8)(B)) furnished to the in-
5 dividual may not exceed the applicable copay-
6 ment amount for the product under the pre-
7 scription drug plan or MA–PD plan in which
8 the individual is enrolled.”; and

9 (B) in subparagraph (E), by inserting the
10 following before the period at the end “or under
11 section 1860D–2(b)(8) in the case of an insulin
12 product (as defined in subparagraph (B) of
13 such section)”; and

14 (2) in paragraph (2)—

15 (A) in subparagraph (D), by adding at the
16 end the following new sentence: “For plan year
17 2023 and subsequent plan years, the amount of
18 the coinsurance applicable under the preceding
19 sentence to an insulin product (as defined in
20 section 1860D–2(b)(8)(B)) furnished to the in-
21 dividual may not exceed the applicable copay-
22 ment amount for the product under the pre-
23 scription drug plan or MA–PD plan in which
24 the individual is enrolled.”; and

1 (B) in subparagraph (E), by adding at the
 2 end the following new sentence: “For plan year
 3 2023, the amount of the copayment or coinsur-
 4 ance applicable under the preceding sentence to
 5 an insulin product (as defined in section
 6 1860D–2(b)(8)(B)) furnished to the individual
 7 may not exceed the applicable copayment
 8 amount for the product under the prescription
 9 drug plan or MA–PD plan in which the indi-
 10 vidual is enrolled.”.

11 (c) IMPLEMENTATION.—The Secretary shall imple-
 12 ment this section for plan years 2023 and 2024 by pro-
 13 gram instruction or otherwise.

14 **SEC. 502. COVERAGE OF ADULT VACCINES RECOMMENDED**
 15 **BY THE ADVISORY COMMITTEE ON IMMUNI-**
 16 **ZATION PRACTICES UNDER MEDICARE PART**
 17 **D.**

18 (a) ENSURING TREATMENT OF COST-SHARING IS
 19 CONSISTENT WITH TREATMENT OF VACCINES UNDER
 20 MEDICARE PART B.—Section 1860D–2 of the Social Se-
 21 curity Act (42 U.S.C. 1395w–102), as amended by section
 22 501, is further amended—

23 (1) in subsection (b)—

1 (A) in paragraph (1)(A), by striking
 2 “paragraph (8)” and inserting “paragraphs (8)
 3 and (9)”;

4 (B) in paragraph (2)(A), by striking
 5 “paragraph (8)” and inserting “paragraphs (8)
 6 and (9)”;

7 (C) in paragraph (3)(A), by striking “and
 8 (8)” and inserting “(8), and (9)”;

9 (D) in paragraph (4)(A)(i), by striking
 10 “paragraph (8)” and inserting “paragraphs (8)
 11 and (9)”;

12 (E) by adding at the end the following new
 13 paragraph:

14 “(9) TREATMENT OF COST-SHARING FOR
 15 ADULT VACCINES RECOMMENDED BY THE ADVISORY
 16 COMMITTEE ON IMMUNIZATION PRACTICES CON-
 17 SISTENT WITH TREATMENT OF VACCINES UNDER
 18 PART B.—

19 “(A) IN GENERAL.—For plan years begin-
 20 ning on or after January 1, 2024, the following
 21 shall apply with respect to an adult vaccine rec-
 22 ommended by the Advisory Committee on Im-
 23 munization Practices (as defined in subpara-
 24 graph (B)):

1 “(i) NO APPLICATION OF DEDUCT-
2 IBLE.—The deductible under paragraph
3 (1) shall not apply with respect to such
4 vaccine.

5 “(ii) NO APPLICATION OF COINSUR-
6 ANCE OR ANY OTHER COST-SHARING.—
7 There shall be no coinsurance or other
8 cost-sharing under this part with respect
9 to such vaccine, regardless of whether for
10 costs below, at, or above the initial cov-
11 erage limit under paragraph (3) or the
12 out-of-pocket threshold under paragraph
13 (4).

14 “(B) ADULT VACCINES RECOMMENDED BY
15 THE ADVISORY COMMITTEE ON IMMUNIZATION
16 PRACTICES.—For purposes of this paragraph,
17 the term ‘adult vaccine recommended by the
18 Advisory Committee on Immunization Prac-
19 tices’ means a covered part D drug that is a
20 vaccine licensed under section 351 of the Public
21 Health Service Act for use by adult populations
22 and administered in accordance with rec-
23 ommendations of the Advisory Committee on
24 Immunization Practices of the Centers for Dis-
25 ease Control and Prevention.”; and

1 (2) in subsection (c), by adding at the end the
2 following new paragraph:

3 “(5) TREATMENT OF COST-SHARING FOR
4 ADULT VACCINES RECOMMENDED BY THE ADVISORY
5 COMMITTEE ON IMMUNIZATION PRACTICES.—The
6 coverage is in accordance with subsection (b)(9).”.

7 (b) CONFORMING AMENDMENTS TO COST-SHARING
8 FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)
9 of the Social Security Act (42 U.S.C. 1395w–114(a)), as
10 amended by section 501, is further amended—

11 (1) in paragraph (1)(D), in each of clauses (ii)
12 and (iii), by striking “In the case” and inserting
13 “Subject to paragraph (6), in the case”;

14 (2) in paragraph (2)—

15 (A) in subparagraph (B), by striking “A
16 reduction” and inserting “Subject to paragraph
17 (6), a reduction”;

18 (B) in subparagraph (D), by striking “The
19 substitution” and inserting “Subject to para-
20 graph (6), the substitution”; and

21 (C) in subparagraph (E), by striking “sub-
22 section (c)” and inserting “paragraph (6) and
23 subsection (c)”; and

24 (3) by adding at the end the following new
25 paragraph:

1 “(6) NO APPLICATION OF COST-SHARING FOR
2 ADULT VACCINES RECOMMENDED BY THE ADVISORY
3 COMMITTEE ON IMMUNIZATION PRACTICES.—For
4 plan years beginning on or after January 1, 2024,
5 there shall be no cost-sharing under this section, in-
6 cluding no annual deductible applicable under this
7 section, with respect to an adult vaccine rec-
8 ommended by the Advisory Committee on Immuniza-
9 tion Practices (as defined in subparagraph (B) of
10 such section).”.

11 (c) RULE OF CONSTRUCTION.—Nothing in this sec-
12 tion shall be construed as limiting coverage under part D
13 of title XVIII of the Social Security Act for vaccines that
14 are not recommended by the Advisory Committee on Im-
15 munization Practices.

16 (d) IMPLEMENTATION FOR 2024.—The Secretary
17 shall implement this section, including the amendments
18 made by this section, for 2024 by program instruction or
19 otherwise.

20 **SEC. 503. PAYMENT FOR BIOSIMILAR BIOLOGICAL PROD-**
21 **UCTS DURING INITIAL PERIOD.**

22 Section 1847A(c)(4) of the Social Security Act (42
23 U.S.C. 1395w–3a(c)(4)) is amended—

24 (1) in each of subparagraphs (A) and (B), by
25 redesignating clauses (i) and (ii) as subclauses (I)

1 and (II), respectively, and moving such subclauses 2
2 ems to the right;

3 (2) by redesignating subparagraphs (A) and
4 (B) as clauses (i) and (ii) and moving such clauses
5 2 ems to the right;

6 (3) by striking “UNAVAILABLE.—In the case”
7 and inserting “UNAVAILABLE.—

8 “(A) IN GENERAL.—Subject to subpara-
9 graph (B), in the case”; and

10 (4) by adding at the end the following new sub-
11 paragraph:

12 “(B) LIMITATION ON PAYMENT AMOUNT
13 FOR BIOSIMILAR BIOLOGICAL PRODUCTS DUR-
14 ING INITIAL PERIOD.—In the case of a bio-
15 similar biological product furnished on or after
16 July 1, 2023, during the initial period described
17 in subparagraph (A) with respect to the bio-
18 similar biological product, the amount payable
19 under this section for the biosimilar biological
20 product is the lesser of the following:

21 “(i) The amount determined under
22 clause (ii) of such subparagraph for the
23 biosimilar biological product.

1 “(ii) The amount determined under
 2 subsection (b)(1)(B) for the reference bio-
 3 logical product.”.

4 **SEC. 504. TEMPORARY INCREASE IN MEDICARE PART B**
 5 **PAYMENT FOR CERTAIN BIOSIMILAR BIO-**
 6 **LOGICAL PRODUCTS.**

7 Section 1847A(b)(8) of the Social Security Act (42
 8 U.S.C. 1395w-3a(b)(8)) is amended—

9 (1) by redesignating subparagraphs (A) and
 10 (B) as clauses (i) and (ii), respectively, and moving
 11 the margin of each such redesignated clause 2 ems
 12 to the right;

13 (2) by striking “PRODUCT.—The amount” and
 14 inserting the following: “PRODUCT.—

15 “(A) IN GENERAL.—Subject to subpara-
 16 graph (B), the amount”; and

17 (3) by adding at the end the following new sub-
 18 paragraph:

19 “(B) TEMPORARY PAYMENT INCREASE.—

20 “(i) IN GENERAL.—In the case of a
 21 qualifying biosimilar biological product
 22 that is furnished during the applicable 5-
 23 year period for such product, the amount
 24 specified in this paragraph for such prod-
 25 uct with respect to such period is the sum

1 determined under subparagraph (A), ex-
2 cept that clause (ii) of such subparagraph
3 shall be applied by substituting ‘8 percent’
4 for ‘6 percent’.

5 “(ii) APPLICABLE 5-YEAR PERIOD.—
6 For purposes of clause (i), the applicable
7 5-year period for a qualifying biosimilar bi-
8 ological product is—

9 “(I) in the case of such a product
10 for which payment was made under
11 this paragraph as of March 31, 2022,
12 the 5-year period beginning on April
13 1, 2022; and

14 “(II) in the case of such a prod-
15 uct for which payment is first made
16 under this paragraph during a cal-
17 endar quarter during the period be-
18 ginning April 1, 2022, and ending
19 March 31, 2027, the 5-year period be-
20 ginning on the first day of such cal-
21 endar quarter during which such pay-
22 ment is first made.

23 “(iii) QUALIFYING BIOSIMILAR BIO-
24 LOGICAL PRODUCT DEFINED.—For pur-
25 poses of this subparagraph, the term

1 ‘qualifying biosimilar biological product’
2 means a biosimilar biological product de-
3 scribed in paragraph (1)(C) with respect to
4 which—

5 “(I) in the case of a product de-
6 scribed in clause (ii)(I), the average
7 sales price under paragraph (8)(A)(i)
8 for a calendar quarter during the 5-
9 year period described in such clause is
10 not more than the average sales price
11 under paragraph (4)(A) for such
12 quarter for the reference biological
13 product; and

14 “(II) in the case of a product de-
15 scribed in clause (ii)(II), the average
16 sales price under paragraph (8)(A)(i)
17 for a calendar quarter during the 5-
18 year period described in such clause is
19 not more than the average sales price
20 under paragraph (4)(A) for such
21 quarter for the reference biological
22 product.”.

23 **SEC. 505. IMPROVING ACCESS TO ADULT VACCINES UNDER**
24 **MEDICAID AND CHIP.**

25 (a) MEDICAID.—

1 (1) REQUIRING COVERAGE OF ADULT VACCINA-
2 TIONS.—

3 (A) IN GENERAL.—Section 1902(a)(10)(A)
4 of the Social Security Act (42 U.S.C.
5 1396a(a)(10)(A)) is amended in the matter pre-
6 ceding clause (i) by inserting “(13)(B),” after
7 “(5),”.

8 (B) MEDICALLY NEEDY.—Section
9 1902(a)(10)(C)(iv) of such Act (42 U.S.C.
10 1396a(a)(10)(C)(iv)) is amended by inserting “,
11 (13)(B),” after “(5)”.

12 (2) NO COST-SHARING FOR VACCINATIONS.—

13 (A) GENERAL COST-SHARING LIMITA-
14 TIONS.—Section 1916 of the Social Security
15 Act (42 U.S.C. 1396o) is amended—

16 (i) in subsection (a)(2)—

17 (I) in subparagraph (G), by in-
18 serting a comma after “State plan”;

19 (II) in subparagraph (H), by
20 striking “; or” and inserting a
21 comma;

22 (III) in subparagraph (I), by
23 striking “; and” and inserting “, or”;
24 and

1 (IV) by adding at the end the fol-
 2 lowing new subparagraph:

3 “(J) vaccines described in section
 4 1905(a)(13)(B) and the administration of such
 5 vaccines; and”; and

6 (ii) in subsection (b)(2)—

7 (I) in subparagraph (G), by in-
 8 serting a comma after “State plan”;

9 (II) in subparagraph (H), by
 10 striking “; or” and inserting a
 11 comma;

12 (III) in subparagraph (I), by
 13 striking “; and” and inserting “, or”;
 14 and

15 (IV) by adding at the end the fol-
 16 lowing new subparagraph:

17 “(J) vaccines described in section
 18 1905(a)(13)(B) and the administration of such
 19 vaccines; and”.

20 (B) APPLICATION TO ALTERNATIVE COST-
 21 SHARING.—Section 1916A(b)(3)(B) of the So-
 22 cial Security Act (42 U.S.C. 1396o–1(b)(3)(B))
 23 is amended by adding at the end the following
 24 new clause:

1 “(xiv) Vaccines described in section
2 1905(a)(13)(B) and the administration of
3 such vaccines.”.

4 (3) INCREASED FMAP FOR ADULT VACCINES.—
5 Section 1905(b) of the Social Security Act (42
6 U.S.C. 1396d(b)) is amended—

7 (A) by striking “and (5)” and inserting
8 “(5)”;

9 (B) by striking “services and vaccines de-
10 scribed in subparagraphs (A) and (B) of sub-
11 section (a)(13), and prohibits cost-sharing for
12 such services and vaccines” and inserting “serv-
13 ices described in subsection (a)(13)(A), and
14 prohibits cost-sharing for such services”;

15 (C) by striking “medical assistance for
16 such services and vaccines” and inserting “med-
17 ical assistance for such services”; and

18 (D) by inserting “, and (6) during the first
19 8 fiscal quarters beginning on or after the effec-
20 tive date of this clause, in the case of a State
21 which, as of the date of enactment of the Act
22 titled ‘An Act to provide for reconciliation pur-
23 suant to title II of S. Con. Res. 14’, provides
24 medical assistance for vaccines described in
25 subsection (a)(13)(B) and their administration

1 and prohibits cost-sharing for such vaccines, the
2 Federal medical assistance percentage, as deter-
3 mined under this subsection and subsection (y),
4 shall be increased by 1 percentage point with
5 respect to medical assistance for such vaccines”
6 before the first period.

7 (b) CHIP.—

8 (1) REQUIRING COVERAGE OF ADULT VACCINA-
9 TIONS.—Section 2103(c) of the Social Security Act
10 (42 U.S.C. 1397cc(c)) is amended by adding at the
11 end the following paragraph:

12 “(12) REQUIRED COVERAGE OF APPROVED,
13 RECOMMENDED ADULT VACCINES AND THEIR AD-
14 MINISTRATION.—Regardless of the type of coverage
15 elected by a State under subsection (a), if the State
16 child health plan or a waiver of such plan provides
17 child health assistance or pregnancy-related assist-
18 ance (as defined in section 2112) to an individual
19 who is 19 years of age or older, such assistance shall
20 include coverage of vaccines described in section
21 1905(a)(13)(B) and their administration.”.

22 (2) NO COST-SHARING FOR VACCINATIONS.—
23 Section 2103(e)(2) of such Act (42 U.S.C.
24 1397cc(e)(2)) is amended by inserting “vaccines de-
25 scribed in subsection (c)(12) (and the administration

1 of such vaccines),” after “in vitro diagnostic prod-
 2 ucts described in subsection (c)(10) (and administra-
 3 tion of such products),”.

4 (c) EFFECTIVE DATE.—The amendments made by
 5 this section take effect on the 1st day of the 1st fiscal
 6 quarter that begins on or after the date that is 1 year
 7 after the date of enactment of this Act and shall apply
 8 to expenditures made under a State plan or waiver of such
 9 plan under title XIX of the Social Security Act (42 U.S.C.
 10 1396 through 1396w–6) or under a State child health plan
 11 or waiver of such plan under title XXI of such Act (42
 12 U.S.C. 1397aa through 1397mm) on or after such effec-
 13 tive date.

14 **TITLE VI—ADDITIONAL INSULIN** 15 **POLICIES**

16 **SEC. 601. ERISA REQUIREMENTS WITH RESPECT TO COST-** 17 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

18 (a) IN GENERAL.—Subpart B of part 7 of subtitle
 19 B of title I of the Employee Retirement Income Security
 20 Act of 1974 (29 U.S.C. 1185 et seq.) is amended by add-
 21 ing at the end the following:

22 **“SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHAR-** 23 **ING FOR CERTAIN INSULIN PRODUCTS.**

24 “(a) IN GENERAL.—For plan years beginning on or
 25 after January 1, 2023, a group health plan or health in-

1 surance issuer offering group health insurance coverage
2 shall provide coverage of selected insulin products, and
3 with respect to such products, shall not—

4 “(1) apply any deductible; or

5 “(2) impose any cost-sharing in excess of the
6 lesser of, per 30-day supply—

7 “(A) \$35; or

8 “(B) the amount equal to 25 percent of
9 the negotiated price of the selected insulin prod-
10 uct net of all price concessions received by or on
11 behalf of the plan or coverage, including price
12 concessions received by or on behalf of third-
13 party entities providing services to the plan or
14 coverage, such as pharmacy benefit manage-
15 ment services.

16 “(b) DEFINITIONS.—In this section:

17 “(1) SELECTED INSULIN PRODUCTS.—The term
18 ‘selected insulin products’ means at least one of each
19 dosage form (such as vial, pump, or inhaler dosage
20 forms) of each different type (such as rapid-acting,
21 short-acting, intermediate-acting, long-acting, ultra
22 long-acting, and premixed) of insulin (as defined
23 below), when available, as selected by the group
24 health plan or health insurance issuer.

1 “(2) INSULIN DEFINED.—The term ‘insulin’
2 means insulin that is licensed under subsection (a)
3 or (k) of section 351 of the Public Health Service
4 Act (42 U.S.C. 262) and continues to be marketed
5 under such section, including any insulin product
6 that has been deemed to be licensed under section
7 351(a) of such Act pursuant to section 7002(e)(4)
8 of the Biologics Price Competition and Innovation
9 Act of 2009 (Public Law 111–148) and continues to
10 be marketed pursuant to such licensure.

11 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
12 this section requires a plan or issuer that has a network
13 of providers to provide benefits for selected insulin prod-
14 ucts described in this section that are delivered by an out-
15 of-network provider, or precludes a plan or issuer that has
16 a network of providers from imposing higher cost-sharing
17 than the levels specified in subsection (a) for selected insu-
18 lin products described in this section that are delivered
19 by an out-of-network provider.

20 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
21 not be construed to require coverage of, or prevent a group
22 health plan or health insurance coverage from imposing
23 cost-sharing other than the levels specified in subsection
24 (a) on, insulin products that are not selected insulin prod-
25 ucts, to the extent that such coverage is not otherwise re-

1 quired and such cost-sharing is otherwise permitted under
 2 Federal and applicable State law.

3 “(e) APPLICATION OF COST-SHARING TOWARDS
 4 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
 5 cost-sharing payments made pursuant to subsection (a)(2)
 6 shall be counted toward any deductible or out-of-pocket
 7 maximum that applies under the plan or coverage.”.

8 (b) CLERICAL AMENDMENT.—The table of contents
 9 in section 1 of the Employee Retirement Income Security
 10 Act of 1974 (29 U.S.C. 1001 et seq.) is amended by in-
 11 serting after the item relating to section 725 the following:

“Sec. 726. Requirements with respect to cost-sharing for certain insulin prod-
 ucts.”.

12 **SEC. 602. PUBLIC HEALTH SERVICE ACT REQUIREMENTS**
 13 **WITH RESPECT TO COST-SHARING FOR INSU-**
 14 **LIN PRODUCTS.**

15 (a) IN GENERAL.—Part D of title XXVII of the Pub-
 16 lic Health Service Act (42 U.S.C. 300gg–111 et seq.) is
 17 amended by adding at the end the following:

18 **“SEC. 2799A–11. REQUIREMENTS WITH RESPECT TO COST-**
 19 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

20 “(a) IN GENERAL.—For plan years beginning on or
 21 after January 1, 2023, a group health plan or health in-
 22 surance issuer offering group or individual health insur-
 23 ance coverage shall provide coverage of selected insulin
 24 products, and with respect to such products, shall not—

1 “(1) apply any deductible; or

2 “(2) impose any cost-sharing in excess of the
3 lesser of, per 30-day supply—

4 “(A) \$35; or

5 “(B) the amount equal to 25 percent of
6 the negotiated price of the selected insulin prod-
7 uct net of all price concessions received by or on
8 behalf of the plan or coverage, including price
9 concessions received by or on behalf of third-
10 party entities providing services to the plan or
11 coverage, such as pharmacy benefit manage-
12 ment services.

13 “(b) DEFINITIONS.—In this section:

14 “(1) SELECTED INSULIN PRODUCTS.—The term
15 ‘selected insulin products’ means at least one of each
16 dosage form (such as vial, pump, or inhaler dosage
17 forms) of each different type (such as rapid-acting,
18 short-acting, intermediate-acting, long-acting, ultra
19 long-acting, and premixed) of insulin (as defined
20 below), when available, as selected by the group
21 health plan or health insurance issuer.

22 “(2) INSULIN DEFINED.—The term ‘insulin’
23 means insulin that is licensed under subsection (a)
24 or (k) of section 351 and continues to be marketed
25 under such section, including any insulin product

1 that has been deemed to be licensed under section
2 351(a) pursuant to section 7002(e)(4) of the Bio-
3 logics Price Competition and Innovation Act of 2009
4 and continues to be marketed pursuant to such li-
5 censure.

6 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
7 this section requires a plan or issuer that has a network
8 of providers to provide benefits for selected insulin prod-
9 ucts described in this section that are delivered by an out-
10 of-network provider, or precludes a plan or issuer that has
11 a network of providers from imposing higher cost-sharing
12 than the levels specified in subsection (a) for selected insu-
13 lin products described in this section that are delivered
14 by an out-of-network provider.

15 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
16 not be construed to require coverage of, or prevent a group
17 health plan or health insurance coverage from imposing
18 cost-sharing other than the levels specified in subsection
19 (a) on, insulin products that are not selected insulin prod-
20 ucts, to the extent that such coverage is not otherwise re-
21 quired and such cost-sharing is otherwise permitted under
22 Federal and applicable State law.

23 “(e) APPLICATION OF COST-SHARING TOWARDS
24 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
25 cost-sharing payments made pursuant to subsection (a)(2)

1 shall be counted toward any deductible or out-of-pocket
2 maximum that applies under the plan or coverage.”.

3 (b) NO EFFECT ON OTHER COST-SHARING.—Section
4 1302(d)(2) of the Patient Protection and Affordable Care
5 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
6 end the following new subparagraph:

7 “(D) SPECIAL RULE RELATING TO INSU-
8 LIN COVERAGE.—The exemption of coverage of
9 selected insulin products (as defined in section
10 2799A–11(b) of the Public Health Service Act)
11 from the application of any deductible pursuant
12 to section 2799A–11(a)(1) of such Act, section
13 726(a)(1) of the Employee Retirement Income
14 Security Act of 1974, or section 9826(a)(1) of
15 the Internal Revenue Code of 1986 shall not be
16 considered when determining the actuarial value
17 of a qualified health plan under this sub-
18 section.”.

19 (c) COVERAGE OF CERTAIN INSULIN PRODUCTS
20 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the
21 Patient Protection and Affordable Care Act (42 U.S.C.
22 18022(e)) is amended by adding at the end the following:

23 “(4) COVERAGE OF CERTAIN INSULIN PROD-
24 UCTS.—

“(A) IN GENERAL.—Notwithstanding paragraph (1)(B)(i), a health plan described in paragraph (1) shall provide coverage of selected insulin products, in accordance with section 2799A–11 of the Public Health Service Act, for a plan year before an enrolled individual has incurred cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year.

“(B) TERMINOLOGY.—For purposes of subparagraph (A)—

“(i) the term ‘selected insulin products’ has the meaning given such term in section 2799A–11(b) of the Public Health Service Act; and

“(ii) the requirements of section 2799A–11 of such Act shall be applied by deeming each reference in such section to ‘individual health insurance coverage’ to be a reference to a plan described in paragraph (1).”.

SEC. 603. IRC REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

(a) IN GENERAL.—Subchapter B of chapter 100 is amended by adding at the end the following new section:

1 **“SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
2 **ING FOR CERTAIN INSULIN PRODUCTS.**

3 “(a) IN GENERAL.—For plan years beginning on or
4 after January 1, 2023, a group health plan shall provide
5 coverage of selected insulin products, and with respect to
6 such products, shall not—

7 “(1) apply any deductible; or

8 “(2) impose any cost-sharing in excess of the
9 lesser of, per 30-day supply—

10 “(A) \$35; or

11 “(B) the amount equal to 25 percent of
12 the negotiated price of the selected insulin prod-
13 uct net of all price concessions received by or on
14 behalf of the plan, including price concessions
15 received by or on behalf of third-party entities
16 providing services to the plan, such as phar-
17 macy benefit management services.

18 “(b) DEFINITIONS.—In this section:

19 “(1) SELECTED INSULIN PRODUCTS.—The term
20 ‘selected insulin products’ means at least one of each
21 dosage form (such as vial, pump, or inhaler dosage
22 forms) of each different type (such as rapid-acting,
23 short-acting, intermediate-acting, long-acting, ultra
24 long-acting, and premixed) of insulin (as defined
25 below), when available, as selected by the group
26 health plan.

1 “(2) INSULIN DEFINED.—The term ‘insulin’
2 means insulin that is licensed under subsection (a)
3 or (k) of section 351 of the Public Health Service
4 Act (42 U.S.C. 262) and continues to be marketed
5 under such section, including any insulin product
6 that has been deemed to be licensed under section
7 351(a) of such Act pursuant to section 7002(e)(4)
8 of the Biologics Price Competition and Innovation
9 Act of 2009 (Public Law 111–148) and continues to
10 be marketed pursuant to such licensure.

11 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
12 this section requires a plan that has a network of providers
13 to provide benefits for selected insulin products described
14 in this section that are delivered by an out-of-network pro-
15 vider, or precludes a plan that has a network of providers
16 from imposing higher cost-sharing than the levels specified
17 in subsection (a) for selected insulin products described
18 in this section that are delivered by an out-of-network pro-
19 vider.

20 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
21 not be construed to require coverage of, or prevent a group
22 health plan from imposing cost-sharing other than the lev-
23 els specified in subsection (a) on, insulin products that are
24 not selected insulin products, to the extent that such cov-
25 erage is not otherwise required and such cost-sharing is

1 otherwise permitted under Federal and applicable State
2 law.

3 “(e) APPLICATION OF COST-SHARING TOWARDS
4 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
5 cost-sharing payments made pursuant to subsection (a)(2)
6 shall be counted toward any deductible or out-of-pocket
7 maximum that applies under the plan.”.

8 (b) CLERICAL AMENDMENT.—The table of sections
9 for subchapter B of chapter 100 is amended by adding
10 at the end the following new item:

“Sec. 9826. Requirements with respect to cost-sharing for certain insulin prod-
ucts.”.

○